Aging and Disease
www.aginganddisease.org
Early access date: January 16, 2026
http://dx.doi.org/10.14336/AD.2025.1477

Perspective

Thrombolysis in Acute Ischemic Stroke: Advances and Prospects

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[Received December 2, 2025; Revised January 14, 2026; Accepted January 15, 2026]

ABSTRACT: This perspective article synthesizes contemporary evidence on advancing thrombolytic strategies for acute ischemic stroke, focusing on extended-window intravenous thrombolysis (IVT) and adjunctive intra-arterial thrombolysis (IAT) during thrombectomy. Future directions for extended-window thrombolysis should integrate artificial intelligence (AI)-powered neuroimaging interpretation to precisely identify the tissue window and quantify hemorrhage risk, while a simplified paradigm based on non-contrast CT and AI collaboration is critical for expanding IVT access in resource-limited settings. For adjunctive IAT, candidate selection should be refined by integrating residual thrombus burden with perfusion status. Collectively, these precision strategies are poised to enhance reperfusion benefits and alleviate the global stroke burden.

Keywords: ischemic stroke, intravenous thrombolysis, intra-arterial thrombolysis

Introduction

Ischemic stroke is characterized by high mortality and disability worldwide [1]. Its acute management relies on prompt reperfusion therapy, primarily via intravenous thrombolysis (IVT) and endovascular thrombectomy (EVT), to salvage the ischemic penumbra. In the global therapeutic landscape where access to EVT remains constrained, the ongoing refinement of thrombolytic protocols is crucial for scalable and cost-effective expansion of reperfusion benefits, particularly in underserved regions. In this narrative review, we integrate contemporary data on extended-window thrombolysis (defined as beyond 4.5 hours from symptom onset, inclusive of unknown onset strokes; **Table 1**) and intra-arterial thrombolytic optimization during thrombectomy (**Table 2**) to clarify current best practice and spotlight the research priorities that will shape the next generation of precision reperfusion therapies (**Fig. 1**).

IVT in extended time window

The time window for IVT is typically limited to 4.5 hours after stroke onset, leaving the majority of patients "time-locked" out of this therapy [2]. In recent years, advances in neuroimaging technology have enabled multimodal imaging to identify patients with salvageable tissue beyond the conventional time window, thereby shifting the paradigm of IVT from a "fixed time window" toward an "individualized tissue window" and expanding the population eligible for benefit. The EXTEND trial marked a pivotal advancement by demonstrating that acute ischemic stroke (AIS) patients within 4.5-9 hours after onset selected by perfusion imaging derived significant benefit from alteplase, showing higher rates of functional independence (modified Rankin Scale [mRS] 0-1) at 90 days compared to placebo [3]. A subsequent meta-analysis of EPITHET, ECASS-4, and EXTEND reinforced this finding and confirmed that the net clinical benefit of IVT with alteplase remained unaffected despite a higher rate of symptomatic intracerebral hemorrhage (sICH) [4]. Parallel to the progress achieved in patients presenting within 4.5-9-hour time window, a series of pivotal trials have established the efficacy of IVT with

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alteplase in those with an unknown time of onset. A meta-analysis of WAKE-UP, EXTEND, THAWS, and ECASS-4 indicated that imaging-selected patients with stroke of unknown time of onset could benefit from alteplase, leading to better 90-day functional outcomes compared to placebo [5].

Table 1. Characteristics of the studies on extended-window IVT.

Study	Country	Treatment time window	Radiological eligibility criteria	Thrombolytic agent	No. of patients (IVT vs control)	Primary outcome	IVT *vs* control group
EPITHET, 2014	Australia, New Zealand, Belgium, and United Kingdom	4.5-6h	NCCT, MRI perfusion: No eligibility criteria based on perfusion-diffusion MRI mismatch	Alteplase	33 vs 30	Infarct growth between baseline DWI and day 90 T2 imaging	94% vs 168%, **P=0.03**
WAKE-UP, 2018	Germany, Denmark, France, Spain, the Netherlands, Belgium, and Australia	≥4.5h	MRI DWI-FLAIR mismatch: DWI with a high signal and visually normal FLAIR	Alteplase	254 vs 249	mRS 0-1	131/246 vs 102/244, **P=0.02**
EXTEND, 2019	Australia, New Zealand, Taiwan, Finland	4.5-9h	MRI or perfusion CT: Perfusion lesion-ischemic core mismatch ratio ≥1.2, an absolute difference in volume >10 mL, and an ischemic core volume <70 mL	Alteplase	113 vs 112	mRS 0-1	40/113 vs 33/112, **P=0.04**
ECASS-4, 2019	Germany, Spain, Australia, Sweden, Italy, United Kingdom, and France	4.5-9h	MRI perfusion: Perfusion lesion-ischemic core mismatch ratio ≥1.2, an absolute difference in volume >10 mL, and an ischemic core volume <70 mL	Alteplase	60 vs 56	mRS shift at day 90	OR=1.200 (0.633-2.273), P=0.58
THAWS, 2020	Japan	≥4.5h	MRI DWI-FLAIR mismatch: DWI with a high signal and visually normal FLAIR	Alteplase	68 vs 58	mRS 0-1	32/68 vs 28/58, P=0.892
ROSE-TNK, 2023	China	4.5-24h	MRI DWI-FLAIR mismatch: DWI with a high signal and visually normal FLAIR, DWI infarct volume <70 mL, DWI region ⩽1/3 of MCA, 1/2 of the ACA, or 1/2 of PCA territories	TNK	40 vs 40	mRS 0-1	21/40 vs 20/40, P=0.82
EXIT-BT, 2024	China	4.5-6h	NCCT or MRI: Confirmed acute ischemic stroke	TNK	50 vs 50	sICH	1/50 vs 0/49, P=0.998
TIMELESS, 2024	the United States and Canada	4.5-24h	CT or MRI perfusion: mismatch ratio at least 1.8, mismatch volume at least 15mL, ischemic core volume less than 70mL	TNK	228 vs 230	Median score on the mRS	3 (1-5) vs 3 (1-4), P=0.45
TRACE-III, 2024	China	4.5-24h	CT or MRI perfusion: mismatch ratio at least 1.8, mismatch volume at least 15mL, ischemic core volume less than 70mL	TNK	264 vs 252	mRS 0-1	87/264 vs 61/252, **P=0.03**

CHABLIS-T II, 2025	China	4.5-24h	CT perfusion: mismatch ratio >1.2, mismatch volume >10mL, ischemic core volume under 70mL	TNK	111 vs 113	Major reperfusion without sICH within 24-48 hours	37/111 vs 12/111, **P=0.001**
EXPECTS, 2025	China	4.5-24h	NCCT: PC-ASPECTS scores ⩾7	Alteplase	117 vs 117	mRS 0-2	103/115 vs 85/117, **P=0.01**
HOPE, 2025	China	4.5-24h	CT perfusion: mismatch ratio at least 1.2, mismatch volume at least 10mL, ischemic core volume less than 70mL	Alteplase	186 vs 186	mRS 0-1	75/186 vs 49/186, **P=0.004**

Abbreviations: ACA: anterior cerebral artery; CHABLIS-T II: Chinese Acute Tissue-Based Imaging Selection for Lysis in Stroke-Tenecteplase II; CT: computed tomography; DWI: diffusion-weighted imaging; ECASS-4: European Cooperative Acute Stroke Study 4; EPITHET: Echoplanar Imaging Thrombolytic Evaluation Trial; EXIT-BT: Extending the Time Window of Thrombolysis by Butyphthalide up to 6 Hours After Onset; EXPECTS: Extending the Time Window for Thrombolysis in Posterior Circulation Stroke without Early CT Signs; EXTEND: Extending the Time for Thrombolysis in Emergency Neurological Deficits; FLAIR: fluid-attenuated inversion recovery; HOPE: Treatment With Intravenous Alteplase in Ischemic Stroke Patients With Onset Time Between 4.5 and 24 Hours; IVT: intravenous thrombolysis; MCA: middle cerebral artery; MRI: magnetic resonance imaging; mRS: modified Rankin Scale; NCCT: noncontrast computed tomography; PCA: posterior cerebral artery; PC-ASPECTS: posterior circulation Acute Stroke Prognosis Early CT Score; ROSE-TNK: MRI-Guided Thrombolysis for Stroke Beyond Time Window by TNK; sICH: symptomatic intracranial hemorrhage; THAWS: Thrombolysis for Acute Wake-Up and Unclear-Onset Strokes With Alteplase at 0.6 mg/kg; TIMELESS: Thrombolysis in Imaging Eligible, Late Window Patients to Assess the Efficacy and Safety of Tenecteplase; TNK: tenecteplase; TRACE-III: Tenecteplase Reperfusion Therapy in Acute Ischemic Cerebrovascular Events-III; WAKE-UP: Efficacy and Safety of MRI-Based Thrombolysis in Wake-Up Stroke.

Strikingly, the subsequent EXPECTS and HOPE trials have demonstrated that IVT with alteplase remained safe and effective within 4.5-24 hours after onset in selected patients with AIS of the posterior and anterior circulation, respectively [6, 7]. These studies provide the first practice-changing evidence to systematically extend the therapeutic window for alteplase to 24 hours, the finding that will undoubtedly inform future updates to global AIS management guidelines. The EXPECTS trial, with its independence from advanced perfusion imaging, holds high potential for dissemination in primary hospitals with limited resources, thereby extending treatment access to numerous posterior circulation stroke patients who have missed the conventional time window. By contrast, the HOPE trial embodies a precision medicine strategy, utilizing computed tomography (CT) perfusion to rigorously select patients with an ischemic penumbra, thereby ensuring both safety and efficacy even in a broader population, including those with distal vessel occlusions. Evidence for the extended time window originates from trials with divergent designs and disparate imaging selection criteria, which might affect the consistency and generalizability of pooled outcomes. In recent, tenecteplase (TNK) has gradually emerged as a pivotal thrombolytic agent in extended-window stroke therapy. A meta-analysis of ROSE-TNK, TIMELESS, TRACE-III, and CHABLIS-T II, which confirmed that TNK administered within 4.5-24 hours significantly improved excellent functional outcomes (mRS 0-1) and arterial recanalization, without elevating sICH or mortality risks [8]. Furthermore, in the extended time window beyond 4.5 hours, TNK was associated with numerically higher odds of excellent functional outcomes compared with alteplase [9]. However, this finding should be interpreted with caution given existing controversies in the field and the lack of confirmatory large-scale clinical trials, and thus the potential role of TNK as a preferred thrombolytic agent for late-presenting patients warrants further validation.

Table 2. Characteristics of the studies on adjunctive IAT during thrombectomy.

Study	Country	Participants	eTICI score	Thrombolytic agent	No. of patients (EVT+IAT vs EVT)	Primary outcome	EVT+IAT vs EVT group, events/total
CHOICE, 2022	Spain	Anterior circulation	2b50-3	Alteplase 0.225 mg/kg	61 vs 52	mRS 0-1	36/61 vs 21/52, **P=0.047**
POST-TNK, 2025	China	Anterior circulation	2c-3	Tenecteplase 0.0625 mg/kg	269 vs 271	mRS 0-1	132/269 vs 119/270, P=0.11
POST-UK, 2025	China	Anterior circulation	2c-3	Urokinase 100,000 IU	267 vs 267	mRS 0-1	120/266 vs 107/266, P=0.19

ATTENTION-IA, 2025	China	Posterior circulation	2b50-3	Tenecteplase 0.0625 mg/kg	104 vs 104	mRS 0-1	36/104 vs 27/104, P=0.12
ANGEL-TNK, 2025	China	Anterior circulation	2b50-3	Tenecteplase 0.125 mg/kg	126 vs 129	mRS 0-1	51/126 vs 34/129, **P=0.02**
DATE, 2025	China	Anterior circulation	2b50-3	Tenecteplase 0.0625/0.03125 mg/kg	92 vs 65	mRS 0-1	20/46 (TNK 0.0625 mg/kg) vs 22/65, P=0.55 17/46 (TNK 0.0313 mg/kg) vs 22/65, P=0.50
PEARL, 2025	China	Anterior circulation	2b50-3	Alteplase 0.225 mg/kg	164 vs 160	mRS 0-1	73/163 vs 48/159, **P=0.01**

Abbreviations: ANGEL-TNK: Intra-arterial Tenecteplase After Successful Endovascular Therapy; ATTENTION: Intra-Arterial Tenecteplase after Successful Endovascular Recanalisation in Patients with Acute Posterior Circulation Arterial Occlusion; CHOICE: Chemical Optimization of Cerebral Embolectomy; DATE: Adjunctive Intra-Arterial Tenecteplase Following Successful Thrombectomy in Patients With Large Vessel Occlusion; eTICI: extended thrombolysis in cerebral infarction; EVT: endovascular thrombectomy; IAT: intra-arterial thrombolysis; PEARL: Intra-arterial Alteplase for Acute Ischaemic Stroke After Mechanical Thrombectomy; POST-TNK: Adjunctive Intra-arterial Tenecteplase Following Near-Complete to Complete Reperfusion for Large Vessel Occlusion Stroke; POST-UK: Adjunctive Intra-Arterial Urokinase After Near-Complete to Complete Reperfusion for Acute Ischemic Stroke.

The decision-making for extended-window thrombolysis hinges primarily on whether imaging assessment can accurately identify salvageable brain tissue even after the "time window has lapsed". What direction will this field take in the future? First, artificial intelligence (AI)-driven automated neuroimaging interpretation to support thrombolytic decisions in extended time window. In TRACE-III trial, deployment of an AI-based acute-stroke imaging platform (iStroke) compressed the imaging evaluation pipeline from over 15 min to just 3 min while extending the efficacy window for IVT to 24 hours for the first time [10].

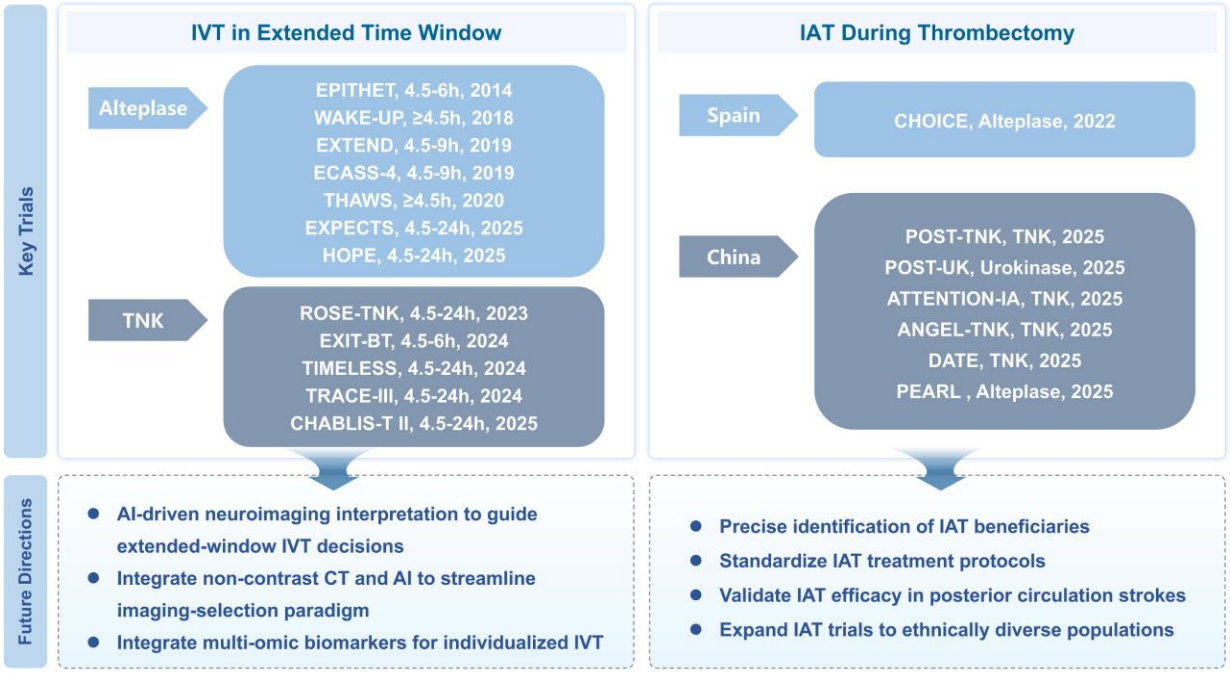

Figure 1. Key trials and future directions in extended-window IVT and IAT during thrombectomy. The upper section synthesizes current clinical evidence through a bipartite structure: the left panel classifies key trials of extended-window IVT according to thrombolytic agent (Alteplase and TNK), whereas the right panel organizes pivotal studies on adjunctive IAT during thrombectomy by trial country (Spain and China). The lower section accordingly outlines future research directions. Abbreviations: AI: artificial intelligence, CT: computed tomography, IAT: intra-arterial thrombolysis, IVT: intravenous thrombolysis, TNK: tenecteplase.

Next-generation algorithms that fuse multimodal neuroimaging with granular clinical covariates are expected to refine selection of ultra-late beneficiaries and to furnish patient-specific estimates of hemorrhagic transformation probability, thereby furnishing a critical decision scaffold for safe extended-window IVT. In addition, implementing AI-based protocols requires necessary personnel training, upgrades to computational

and imaging infrastructure, and ongoing technical support, all of which impose significant financial and logistical burdens, particularly in under-resourced healthcare settings. Therefore, advancing AI-assisted decision-making must be coupled with efforts to develop cost-effective, scalable implementation models and to strengthen corresponding health system capacities to ensure equitable and sustainable adoption. Secondly, streamlining the imaging-selection paradigm through the integration of non-contrast CT and AI. This will be achieved by developing deep-learning models that predict tissue fate. By analyzing plain CT scans and clinical data, these frameworks synthesize imaging features to estimate the likelihood of salvageable penumbra, effectively simulating a mismatch assessment without the immediate need for advanced imaging. This simplified approach will equip primary-level hospitals to select candidates for extended-window thrombolysis and materially expand the accessibility and population-wide penetration of stroke reperfusion therapy. Thirdly, integration of biomarkers toward truly individualized thrombolysis. Emerging evidence indicates that circulating biomarkers can function as a "molecular clock", enabling precise estimation of stroke onset and thereby transcending conventional time windows. For example, metabolomic candidates such as biliverdin and nicotinamide N-oxide have shown high discriminative accuracy in distinguishing stroke onset beyond 4.5 hours [11]. Nevertheless, clinical translation of such biomarkers faces substantial hurdles, including the intrinsic time-sensitivity of their release kinetics, assay cost and variability, and the absence of rapid, standardized point-of-care platforms. In addition, to further advance toward clinical implementation, future work could pursue two complementary strands: first, the validation of multi-omic biomarker panels in large, prospective cohorts to establish robustness and generalizability; and second, the development of integrated decision frameworks that fuse selected biomarker profiles with neuroimaging signatures, such as perfusion-diffusion mismatch or collateral status, to generate a composite tissue-viability profile. Together, this biomarker-imaging synergy aims to enable patient-specific thrombolytic strategies in the extended time window, shifting the paradigm from purely chronological to pathophysiology-guided therapy.

Intra-arterial thrombolysis during thrombectomy

Despite successful recanalization rates exceeding 70% with EVT, nearly half of patients with large vessel occlusion (LVO) fail to achieve functional independence, a discrepancy potentially attributable to impaired microcirculatory perfusion [12]. Intra-arterial thrombolysis (IAT) has been proposed to address this issue. The CHOICE trial, a pioneering randomized controlled study, provided pivotal evidence that IAT with alteplase after successful EVT can significantly improve functional independence (mRS 0-1) at 90 days, sparking hope for this strategy [13]. However, subsequent randomized controlled trials (RCTs) have reported inconsistent results. A meta-analysis incorporating data from the CHOICE, POST-TNK, POST-UK, ATTENTION-IA, ANGEL-TNK, DATE, and PEARL trials demonstrated that adjunctive IAT following successful EVT in LVO-AIS patients significantly increased the rate of excellent functional outcome (mRS 0-1), without increasing the risks of sICH or 90-day mortality [14]. The promising findings warrant cautious interpretation due to heterogeneity across trials. This variability encompasses discrepancies in the definitions of successful recanalization (eTICI 2b50-3 versus 2c-3), inconsistencies in IAT protocols (e.g., thrombolytic agent selection, dosing regimens, and administration strategies), and differences in the sites of vascular occlusion (anterior versus posterior circulation). Together with population bias and the absence of long-term outcome data, these methodological limitations might restrict the broader applicability of the findings and highlight the necessity of developing standardized, globally inclusive clinical trials. Therefore, the broader implementation of adjunctive IAT still faces several challenges. First, which patients are the optimal candidates for IAT? Current studies differ in the definitions of successful recanalization in EVT, with standards ranging from eTICI 2b50-3 to the more stringent eTICI 2c-3. Subgroup analyses revealed a higher rate of favorable functional outcome (mRS 0-1) in the eTICI 2b50-3 subgroup than in the eTICI 2c-3 subgroup [14]. This prompts us to reflect that the benefits of IAT may not be universal, but rather manifest in patients with clear and intervenable "residual microcirculatory impairment" after EVT. For patients with eTICI 2c-3 who have near-complete recanalization, the potential benefit of additional IAT might be limited. Therefore, future efforts should focus on accurately identifying potential IAT beneficiaries based on real-time angiographic assessment of residual thrombus burden and perfusion status, moving away from a one-size-fits-all strategy toward truly individualized care. Secondly, current studies on adjuvant IAT after EVT are trapped in the dilemma of significant protocol heterogeneity. There are inconsistencies in the selection of thrombolytic agents (alteplase, TNK, urokinase) and their doses (e.g., TNK doses range from 0.03125mg/kg to 0.125mg/kg), as well as in administration methods (rapid bolus injection or 10-30 minute infusion) and sites (proximal to the occlusion or distal to the branches). The current fragmented landscape underscores the imperative for definitive, multicenter trials with homogeneous protocols to establish a

standardized treatment pathway. Thirdly, current evidence for adjunctive IAT comes almost exclusively from anterior circulation strokes, leaving its efficacy in posterior circulation outside the ATTENTION-IA trial an open question that the ongoing IAT-TOP study seeks to resolve with high-quality data. Finally, existing RCTs have been conducted predominantly in China and Spain, leaving their generalizability to other ethnic groups uncertain. Given that differences in stroke pathophysiology, genetic backgrounds, and healthcare infrastructure across regions could critically affect therapeutic efficacy and safety, definitive evidence necessitates validation in more ethnically diverse populations.

Conclusion

In AIS patients, extended-window thrombolysis and adjunctive IAT during thrombectomy have achieved substantial progress. Future extended-window thrombolysis should integrate AI-powered neuroimaging interpretation to precisely identify the tissue window and quantify hemorrhage risk to guide thrombolytic decisions, while a simplified paradigm based on non-contrast CT and AI collaboration is envisioned in resource-limited settings to materially expand the IVT accessibility. For adjunctive IAT, candidate selection should be refined by integrating residual thrombus burden with perfusion status to pinpoint patients most likely to benefit, while optimal drug choice, dosage, and administration protocols remain to be established. Collectively, these measures are poised to enhance the benefits of reperfusion therapy, thereby alleviating the disease burden of stroke.

Acknowledgements

This study was supported by National Natural Science Foundation of China (82271312), Noncommunicable Chronic Diseases-National Science and Technology Major Project (2024ZD0527600, 2024ZD0527603), and National Key Research and Development Program of China (2023YFC2506504).

Author Contributions

Zixin Wang: Conceptualization, investigation, and writing-original draft. Jiamin Li, Yun Chen, and Boyi Yuan: Investigation and data curation. Qingfeng Ma: Conceptualization, supervision, writing-review & editing, funding acquisition and resources.

Competing interests

The authors declare no competing interests.

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