

Current Research in Neurology and Neurosurgery

Review Article

Endovascular Thrombectomy Beyond Six Hours in Anterior Circulation Large Vessel Occlusion

Dvorak O^{1*}, Golob M² and Antoniou E³

¹Department of Stroke Medicine, Masaryk University, Brno, Czech Republic

²Department of Interventional Neuroradiology, University of Ljubljana, Ljubljana, Slovenia

³Department of Neurology, Aristotle University of Thessaloniki, Thessaloniki, Greece

*Address for Correspondence: Ondrej Dvorak, Department of Stroke Medicine, Masaryk University, Brno, Czech Republic; E-mail: ondrej.dvorak@masarykuniiversity.edu

Received: 12 July 2023; Accepted: 2 October 2023; Published: 26 December 2023; DOI: 10.5281/zenodo.22310336

Citation of this article: Dvorak O, Golob M and Antoniou E (2023) Endovascular Thrombectomy Beyond Six Hours in Anterior Circulation Large Vessel Occlusion. Curr Res Neurol Neurosurg, 6(1): 01-08.

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Abstract

Background: Mechanical thrombectomy is standard of care for anterior-circulation large vessel occlusion (LVO) stroke treated within roughly six hours of onset, but many patients present later or with unknown onset time.

Objective: To review trial and post-trial evidence for thrombectomy beyond six hours, including wake-up stroke.

Methods: Narrative review of randomised trials, pooled analyses, imaging-selection studies, registries and guidelines.

Findings: DAWN and DEFUSE 3 used clinical-core and perfusion mismatch, respectively, to select patients 6-24 hours from onset, each halted early for efficacy, with functional-independence rates roughly triple those of medical management. The AURORA meta-analysis and MR CLEAN-LATE, using simpler collateral-based imaging, confirmed and extended this benefit. Number-needed-to-treat for functional independence is approximately 3-4. Registry data show growing, cost-effective real-world uptake. Symptomatic haemorrhage and futile recanalisation remain relevant harms.

Conclusions: Imaging-based, not clock-based, selection extends thrombectomy's benefit well beyond six hours and is now incorporated into major guidelines, though optimal imaging strategy and patient selection remain active areas of refinement.

Keywords: Thrombectomy; Large vessel occlusion; Extended time window; Wake-up stroke; Perfusion imaging

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Introduction

Mechanical thrombectomy became standard of care for anterior-circulation large vessel occlusion (LVO) stroke after five trials published in 2015 — MR CLEAN [1], ESCAPE [2], EXTEND-IA [3], SWIFT PRIME [4], and REVASCAT [5] — each stopped early for efficacy after showing large absolute gains in functional independence over medical management alone. Pooled in the HERMES individual-patient-data meta-analysis of these five trials,

thrombectomy produced a number needed to treat of roughly 2.6 for improved disability outcome across the whole modified Rankin scale (mRS), but treatment began within about six hours of onset in nearly all enrolled patients [6]. A subsequent HERMES analysis of time-to-treatment showed the odds of good outcome fell steeply with each additional hour of delay within that early window, reinforcing "time is brain" as the guiding clinical principle and seemingly closing the door on treatment initiated substantially later [7].

Yet a substantial minority of patients retain salvageable ischaemic tissue well beyond six hours, because collateral circulation and the rate of infarct-core growth vary considerably between individuals. Two trials published in 2017-2018, DAWN and DEFUSE 3, tested whether selecting patients by advanced brain imaging rather than by the clock could identify this group and extend the demonstrated benefit of thrombectomy out to 16-24 hours after onset [8,9,10]. Their results, alongside subsequent pooled analyses, registries and a further pragmatic trial using simplified imaging, have reshaped stroke systems of care worldwide by decoupling eligibility from a fixed time cut-off. This narrative review synthesises the trial and post-trial literature on extended-window thrombectomy in anterior-circulation LVO, including wake-up stroke as a special case, the resulting functional outcomes and their number-needed-to-treat, relevant complications and patient-selection caveats, and current guideline recommendations.

The Extended Time-Window Concept and Imaging Selection

The extended-window paradigm rests on distinguishing the irreversibly infarcted "core" from still-salvageable "penumbra," and on recognising that the pace at which core expands into penumbra differs greatly between patients depending on collateral supply. Diffusion-weighted MRI (DWI) with fluid-attenuated

inversion recovery (FLAIR) mismatch was first validated as a surrogate marker of stroke recency in the multicentre PRE-FLAIR study, in which a DWI-positive, FLAIR-negative lesion predicted onset within roughly 4.5 hours with reasonable specificity [11]. This DWI-FLAIR concept underpins the imaging strategy used to select unknown-onset patients for reperfusion therapy. The companion concept of perfusion-diffusion "target mismatch" — a small DWI or CT-defined core together with a substantially larger volume of hypoperfused, at-risk tissue on perfusion imaging — was validated as predicting benefit from late endovascular reperfusion in the prospective DEFUSE 2 cohort study [12], and this profile directly informed the automated perfusion thresholds later used as DEFUSE 3's enrolment criteria.

Because infarct-growth rate is highly variable, imaging-selected patients treated later can show effect sizes as large as, or even larger than, those treated earlier — a phenomenon termed the "late window paradox": patients who remain trial-eligible at 12-24 hours are, almost by definition, slow progressors with comparatively more salvageable tissue remaining [13]. This observation, together with the DAWN and DEFUSE 3 results themselves, prompted an influential call to shift from a purely time-based to a tissue-based, or "tissue clock," selection paradigm across acute stroke care generally [14]. Subsequent work has questioned whether perfusion or MRI imaging is strictly necessary to realise this benefit: a large multinational cohort of 1604 patients found no significant difference in 90-day disability outcome, functional independence, or symptomatic haemorrhage when patients were selected by noncontrast CT alone versus CT perfusion or MRI in the 6-24 hour window, suggesting that simpler, more widely available imaging pathways may suffice in many centres that lack round-the-clock perfusion software [15].

Key Trial Evidence: DAWN and DEFUSE 3

Table 1: Design, eligibility and key outcomes of the DAWN and DEFUSE 3 trials [8,9].		
Feature	DAWN	DEFUSE 3
Time window	6-24 hours from last known well	6-16 hours from last known well
Imaging selection	Clinical deficit (NIHSS) vs infarct-core volume mismatch	Perfusion (CTP/MRI) vs infarct-core volume mismatch
Core volume threshold	Age- and NIHSS-adjusted (<21-51 mL)	<70 mL, with ≥1.8-fold, ≥15 mL mismatch
Sample size	206 patients	182 patients
Occlusion sites	Intracranial ICA and/or MCA-M1	Intracranial ICA and/or MCA-M1
Functional independence (mRS 0-2), EVT vs control	49% vs 13%	45% vs 17%
90-day mortality, EVT vs control	19% vs 18%	14% vs 26%
Symptomatic ICH, EVT vs control	6% vs 3%	7% vs 4%
Trial status	Stopped early for efficacy	Stopped early for efficacy

DAWN (DWI or CTP Assessment with Clinical Mismatch in the Triage of Wake-Up and Late Presenting Strokes Undergoing Neurointervention) randomised 206 patients with anterior-circulation LVO 6-24 hours from last known well, selected by an age-adjusted mismatch between clinical deficit severity (NIHSS) and infarct-core volume on CT or MR perfusion imaging. Thrombectomy produced a mean utility-weighted mRS improvement of 2.0 points and a functional-independence (mRS 0-2) rate of 49% versus 13% with medical management alone (adjusted difference 33 percentage points), without a significant increase in mortality or symptomatic haemorrhage [8].

DEFUSE 3 randomised 182 patients 6-16 hours from onset using automated CT or MR perfusion software to identify a small ischaemic core (<70 mL) together with a substantial (≥1.8-fold, ≥15 mL) mismatch to the hypoperfused volume. Functional independence was achieved in 45% of the thrombectomy group versus 17% of

the medical-management group (odds ratio 2.67), and 90-day mortality was numerically lower with thrombectomy (14% versus 26%), again with no significant excess of symptomatic haemorrhage (7% versus 4%) [9]. Both trials were stopped early by their independent data safety monitoring boards for overwhelming efficacy, and both used the same automated perfusion software (RAPID) for real-time eligibility assessment at the point of care — a practical enabler that allowed rapid, reproducible translation of the mismatch concept into everyday clinical workflow [10]. Because DAWN enrolled a somewhat older, more clinically severe population using clinical-core mismatch while DEFUSE 3 enrolled a broader population using perfusion mismatch, the two trials are complementary rather than duplicative, and most guideline eligibility criteria now reference both sets of thresholds together.

Outcomes and Number-Needed-to-Treat

Across DAWN and DEFUSE 3, the absolute difference in functional independence was 33-36 percentage points, corresponding to a number needed to treat of roughly 3-4 for one additional patient achieving independence — a magnitude comparable to, or larger than, that seen in the early-window HERMES trials (NNT $\approx$ 2.6) despite the substantially longer delay to treatment [6]. A dedicated random-effects meta-analysis pooling DAWN and DEFUSE 3 confirmed consistent benefit across age strata (above and below 80 years) and across wake-up versus known-onset subgroups, with no significant heterogeneity between the two trials [16]. The subsequent AURORA collaboration performed an individual-patient-data meta-analysis of six extended-window randomised trials (n=505) and confirmed a robust overall treatment effect on the ordinal mRS shift, with no significant interaction by time from last known well within the 6-24 hour window [17]; a 2026 follow-up analysis from the same collaboration, examining time-to-treatment specifically

within this extended cohort, showed that benefit is consistently preserved across the full 6-24 hour window rather than declining with delay, reflecting the validity of physiological (tissue-based) selection rather than a simple insensitivity of outcome to time [18]. Economic modelling reaches a pragmatically concordant conclusion: extended-window thrombectomy has a greater than 99.9% probability of being cost-effective against standard medical care at conventional willingness-to-pay thresholds, supporting health-system investment in the imaging and workflow infrastructure needed to deliver it [19].

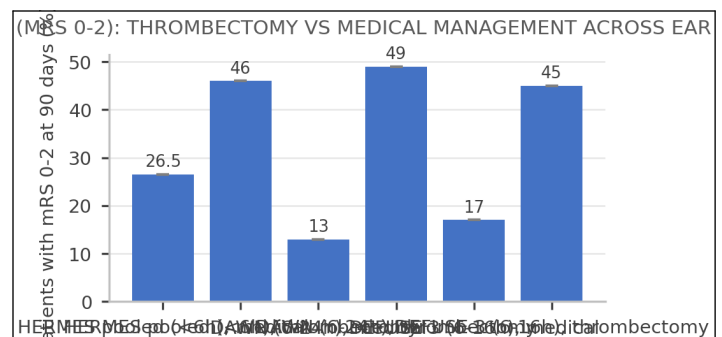


Figure 1: 90-day functional independence (mRS 0-2) with thrombectomy versus medical management: HERMES pooled early-window trials (46.0% vs 26.5%) [6]; DAWN, 6-24h (49% vs 13%) [8]; DEFUSE 3, 6-16h (45% vs 17%) [9].

Wake-Up Stroke as a Special Case

Roughly one-quarter to one-third of ischaemic strokes are first recognised on waking, leaving true onset time unknown and historically excluding these patients from any time-based reperfusion therapy altogether, regardless of how much salvageable tissue remained. Wake-up strokes made up a substantial proportion of both DAWN and DEFUSE 3 enrolment — over half of patients in pooled extended-window trial cohorts — and outcomes in this subgroup closely mirrored those with a known, documented onset time, providing direct support for imaging-based rather than clock-based eligibility in this population [8,9,17]. For intravenous thrombolysis specifically, the analogous WAKE-UP trial used

DWI-FLAIR mismatch to select unknown-onset patients for alteplase, showing better 90-day functional outcome than placebo, albeit with a numerically higher rate of symptomatic haemorrhage and of death [20]; in contemporary practice, wake-up patients with a confirmed LVO on vascular imaging are triaged directly to thrombectomy pathways using the same underlying mismatch principles rather than being managed with thrombolysis alone. Nationwide registry data corroborate this shift in practice: in Sweden, the proportion of all anterior-circulation thrombectomies performed beyond six hours rose from 17% in 2015 to 33% in 2020, and by 2020 nearly one-third of all thrombectomies performed nationally were in this late window, with functional and safety outcomes broadly comparable to the pivotal trial cohorts [21].

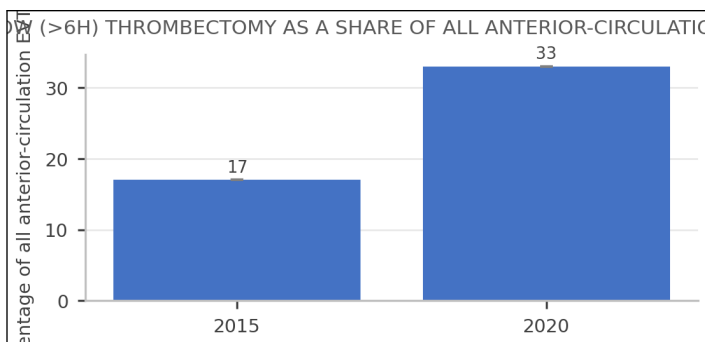


Figure 2: Late-window (>6h) thrombectomy as a share of all anterior-circulation thrombectomy procedures in the Swedish national stroke registry, 2015 versus 2020 (17% vs 33%) [21].

Complications and Patient Selection Caveats

Extended-window thrombectomy is not free of harm, and its benefits depend on careful adherence to imaging-based selection rather than time alone. Both DAWN and DEFUSE 3 showed numerically higher, though not statistically significant, rates of symptomatic intracranial haemorrhage with thrombectomy compared with medical management, and imaging-based selection does not eliminate "futile recanalisation," in which technically successful reperfusion (mTICI 2b-3) fails to

translate into functional independence, an outcome that remains disproportionately common in older patients, those with larger residual infarct cores, and those experiencing longer delays to reperfusion despite otherwise meeting trial criteria. General anaesthesia during thrombectomy has been associated with modestly worse functional outcomes than conscious sedation or local anaesthesia in pooled individual-patient-data analysis of the earlier HERMES trials, a practical peri-procedural consideration reasonably extrapolated to extended-window practice given the longer, often more fragile, ischaemic tissue involved [22]. The comparable outcomes reported across noncontrast CT, CT perfusion, and MRI selection are reassuring for centres lacking around-the-clock advanced perfusion software, but caution is warranted before extrapolating this equivalence to patients with larger cores, more severe deficits, or longer delays than those studied [15]. MR CLEAN-LATE, which selected purely on the presence of collateral flow on CT angiography without formal core-volume or perfusion-mismatch quantification, also demonstrated clear benefit in the 6-24 hour window, further supporting the feasibility of simplified selection pathways while underscoring that trial-specific eligibility criteria are not necessarily interchangeable and should be applied as tested [23].

Current Guideline Recommendations

The 2018 American Heart Association/American Stroke Association (AHA/ASA) acute ischaemic stroke guideline was the first major guideline to incorporate DAWN and DEFUSE 3, recommending mechanical thrombectomy in carefully selected patients presenting 6-24 hours from last known well who meet either the DAWN or the DEFUSE 3 eligibility criteria [24], with the recommendation refined and its evidentiary basis expanded in the 2019 update as further supporting literature accumulated [25]. The European Stroke Organisation-European Society for

Minimally Invasive Neurological Therapy (ESO-ESMINT) mechanical thrombectomy guideline reached concordant conclusions independently, similarly issuing a strong recommendation for thrombectomy in the extended window among imaging-selected patients meeting trial criteria [26]. Both bodies explicitly note that the evidence base continues to evolve, particularly regarding whether simplified (noncontrast CT-based or collateral-based) imaging selection can safely substitute for perfusion or MRI mismatch outside the settings in which it has so far been studied, and regarding applicability to patients who fall outside strict randomised-trial eligibility criteria.

Table 2: Major guideline recommendations for extended-window (>6h) endovascular thrombectomy in anterior-circulation large vessel occlusion stroke [24,25,26].

Guideline (year)	Time window endorsed	Selection basis	Key recommendation	Source
AHA/ASA (2018)	6-24 hours	DAWN or DEFUSE 3 imaging criteria	Thrombectomy recommended in selected patients	power s2018
AHA/ASA 2019 update	6-24 hours	DAWN or DEFUSE 3 imaging criteria, refined	Recommendation strengthened with added trial data	power s2019
ESO-ESMINT (2019)	6-24 hours	Clinical-core or perfusion mismatch	Strong recommendation in imaging-selected patients	turc2019

Conclusion

DAWN and DEFUSE 3 established that imaging-based patient selection, rather than a fixed treatment-window cut-off, identifies a substantial population of patients who benefit from thrombectomy up to 24 hours after anterior-circulation LVO stroke onset, including those with wake-up stroke and unknown onset time. Subsequent individual-patient-data pooled analyses, national registry data, and the pragmatic MR CLEAN-LATE trial have reinforced and broadened this evidence base, while comparative imaging studies suggest that simpler, more widely available selection pathways

may extend access to this therapy without sacrificing safety or efficacy. Major guidelines now formally endorse extended-window thrombectomy in appropriately selected patients, though optimal imaging strategy, better prediction and mitigation of futile recanalisation, and the applicability of trial evidence to patients outside strict eligibility criteria remain active and clinically important areas of ongoing investigation.

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