MILESTONES OF ACUTE ISCHAEMIC STROKE CARE:
REAL-LIFE EVIDENCE ON THE IMPACT OF AI-BASED DECISION-SUPPORT, COVID-19 PANDEMIC AND OF EXTENSION OF THE THERAPEUTIC TIME WINDOWS FOR ACUTE REPERFUSION THERAPIES

PhD thesis

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1. Introduction

Stroke is a leading cause of mortality and disability worldwide, contributing to 143 million Disability Adjusted Life Years (DALYs) in 2019. In 2021, the total cost of stroke in 27 EU countries was approximately 110 billion euros, with significant portions attributed to healthcare expenses, social costs, and lost productivity.

Despite advances in acute stroke reperfusion therapies, only about 7.3% of acute ischaemic stroke (AIS) patients in Europe receive intravenous thrombolysis (IVT), and about 2% receive endovascular therapy (EVT), with considerable inter- and intra-country availability differences. These therapies are the most effective treatment options for AIS, and patient eligibility significantly impacts long-term outcomes. Expanding the time windows (TWs) for reperfusion therapies has offered life-changing opportunities for selected patients based on advanced imaging.

Interpreting computed tomography (CT) findings can be inconsistent due to varying expertise and inter-rater variability. Additionally, coordinating interhospital communication in stroke centres using the drip-and-ship model is operationally challenging. AI-assisted decision support solutions help detect ischaemic areas, measure infarct core and penumbra volume, and identify large vessel occlusion (LVO) using CT, CT angiography (CTA) and CT perfusion (CTP). They also provide a communication platform for interdisciplinary care.

EVT transformed AIS care in 2015, with multiple trials demonstrating positive outcomes for LVO patients. At that time, the effectiveness of EVT was found to decrease with each passing hour after symptom onset, emphasizing the "time is brain" principle. Thus, the January 2018 AHA/ASA guidelines recommended EVT up to 6 hours from symptom onset.

Perfusion imaging played a key role in extending TWs for acute reperfusion therapies, shifting from a strict time-based

approach to a more personalized one based on individual pathophysiology. The DAWN and DEFUSE 3 trials showed clear benefits of EVT within 6 to 24 hours from stroke onset, leading to updated guidelines recommending extended TW for EVT up to 24 hours. MRI and CT perfusion have become crucial for identifying eligible AIS patients for late treatments. MRI is particularly useful for unknown onset strokes, as demonstrated in the WAKE-UP and EXTEND trials, which established the basis for extended TW IVT up to 9 hours from symptom onset.

The COVID-19 pandemic hindered the rapid advancement of AIS care, affecting IVT and EVT resources, perfusion imaging availability, and transport times. Research showed an overall stroke risk of 1.5% associated with COVID-19, with severe infections linked to higher stroke risk. COVID-19 increases the risk of ischaemic stroke through various pathophysiological mechanisms, resulting in worse outcomes.

The Action Plan for Stroke in Europe aims to treat at least 90% of stroke patients in stroke units, achieve 95% availability of acute reperfusion therapies, and reach a 15% IVT rate and over 5% EVT rate by 2030. This requires a conscious organization of stroke care, considering real-life data and ongoing research to effectively plan pathways and resources.

We aim to provide an overview of data spanning six years of AIS care at a university stroke centre in Hungary, where MRI has been routinely used as advanced imaging in acute stroke for the first time in the country.

This work presents four studies, highlighting changes in stroke protocols and the impact of the COVID-19 pandemic on AIS care:

1. AIS care using AI-based decision support
2. Experience on extending the thrombectomy TW
3. The impact of COVID-19 infection on AIS outcome
4. Extending the TW for both thrombolysis and thrombectomy

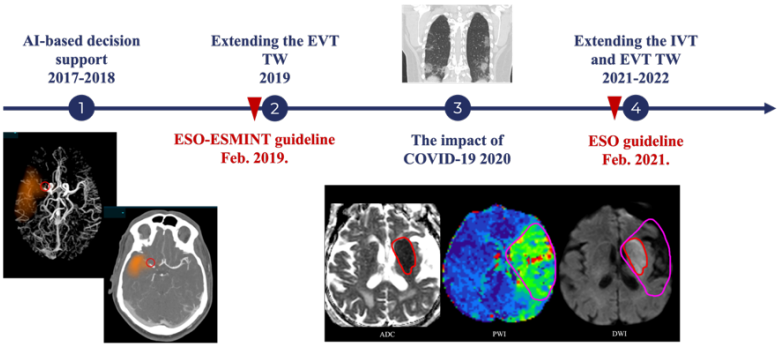

Figure 1. Timeline of the four studies

2. Objectives

Our research aims to provide real-world data on the effects of AI-based decision support, on the impact of COVID-19 on AIS prognosis, and the clinical workload and treatment effects of extending acute reperfusion therapy TWs.

We aim to enhance patient outcomes and streamline stroke care practices by assisting healthcare professionals and management in resource planning across the entire stroke pathway. We argue that integrating AI, advanced imaging and focusing on a multidisciplinary approach can improve AIS care strategies.

3. Methods

All research was conducted at the Department of Neurology, Semmelweis University, Budapest, Hungary, a primary stroke centre capable of IVT but not EVT. EVT was provided in a drip-and-ship model at the Department of Neurosurgery and Neurointervention, Semmelweis University located 8 km away, which was not integrated into the university network at the time. This comprehensive stroke centre, the only EVT centre in the capital and Central Hungary, used a different hospital information and picture archiving system, making data transfer challenging. Initial neurological exams were conducted

at the Department of Emergency Medicine, Semmelweis University, in a different building from the Department of Neurology. The data collected were analyzed using appropriate statistical methods after testing for normal distribution, with significance set at $p<0.05$.

3.1. AIS care using AI-based decision support

Between May and December of 2017 and 2018, data from all AIS patients at Semmelweis University Department of Neurology were retrospectively analyzed. Patients were selected for reperfusion treatment based on international and local guidelines at the time, with IVT considered for those presenting within 4.5 hours of stroke onset and thrombectomy for those with an ASPECTS score >5 and large vessel occlusion (LVO) in the internal carotid artery (ICA), middle cerebral artery (MCA) or basilar artery (BA). In May 2018, the Brainomix e-Stroke Suite software was implemented and used for acute stroke care. Data collected included demographics, treatment times, NIHSS on admission, and mRS at 90 days. Non-contrast CT and CTA were performed, with e-ASPECTS and e-CTA analysis used to assess ischaemic regions, LVOs and collateral flow. Statistical analyses evaluated changes in reperfusion therapy, door-to-treatment times, and outcomes. This retrospective review did not require ethical approval or informed consent.

3.2. Experience on extending the thrombectomy TW

From February 1 to December 31, 2019, all AIS patients admitted within 24 hours of onset were included in the study following the 2019 ESO-ESMINT guidelines. Emergency Medical Services (EMS) transported acute stroke patients with symptom onset within 6 hours to the stroke centre. Non-invasive angiography was routinely performed for all patients in the standard TW, but not in the extended TW. EVT eligibility in the

standard TW required occlusion of ICA, MCA, anterior cerebral artery (ACA) A1 segment or posterior cerebral artery (PCA) P1 segment with ASPECTS ≥ 6. In the 6-24 hour TW, only patients with NIHSS ≥ 6 or fluctuating/brainstem symptoms and premorbid mRS ≤ 2 underwent CTA, and those with ICA, M1 or BA occlusions underwent MRI to identify DWI-PWI mismatch. Patients with unknown onset strokes recognized within 4 hours had primarily MRI. In the case of DWI-FLAIR mismatch, they were included in the standard; otherwise, they were included in the extended TW group. EVT eligibility was determined by DEFUSE 3 criteria (6-16 hours) and simplified DAWN criteria (16-24 hours)

Data collected included TW, age, NIHSS, non-invasive angiography use, presence of LVO, and EVT use. Clinical outcomes at 3 months were assessed, and comparisons between the 0-6 and 6-24 hour windows were performed. The study was approved by the Semmelweis University Ethics Committee (SE-RKEB 17/2020), and no informed consent was obtained due to its observational nature.

3.3. The impact of COVID-19 infection on AIS outcome

We analyzed data from 32 AIS patients with COVID-19 (March 2020 - May 2021) and 51 non-COVID-19 AIS patients (October 2020) at Semmelweis University Department of Neurology with confirmed ischaemia either on CT or MRI. COVID-19 AIS patients had positive SARS-CoV-2 tests within two weeks of stroke onset. Pneumonia was assessed on chest CT or X-ray. The COVID-19 infection was classified based on the World Health Organisation (WHO) COVID-19 severity classification. Data was collected retrospectively from medical documentation, the analysis included demographics, medical history, stroke characteristics, laboratory results, hospitalization length, mRS at discharge, in-hospital mortality, and intensive care unit (ICU) transfer. This study was approved by

Semmelweis University Regional and Institutional Committee of Science and Research Ethics (No.: 201/2021). Informed consent was not sought because of its observational and retrospective nature.

3.4. Extending the TW for both thrombolysis and thrombectomy

Implementing the February 2021 ESO guidelines, from March 1, 2021, to February 28, 2022, we collected data from all AIS or transient ischaemic attack (TIA) patients presenting within 24 hours of symptom onset at Semmelweis University Stroke Centre. EMS protocols required transporting suspected stroke patients within 24 hours to the nearest stroke centre. Neurological examinations were performed in the Emergency Department, with multimodal MRI as the first-choice imaging during working hours (08-20 h), and CT/CTA used otherwise. Reperfusion treatment eligibility followed ESO guidelines, with specific criteria for extended TW therapies based on advanced imaging. Collected data included demographics, stroke onset time, NIHSS, imaging modality, door-to-imaging time (DIT), presence and location of LVO, door-to-needle time (DNT), door-to-groin time (DGT), recanalization rate, EVT complications, and mRS at 90 days. The study was approved by the Semmelweis University Regional and Institutional Committee of Research Ethics (approval no. 123/2019), with patient consent obtained only for off-label Actilyse use in the extended thrombolysis TW.

4. Results

4.1 AIS care using AI-based decision support

During the May to December period of 2017, 399 patients were admitted. On May 11th, 2018, the AI-based

decision support software Brainomix was implemented. In the corresponding period in 2018, we analysed the data of 398 patients. Baseline demographics showed no significant difference between the two years. In 2017, among the 46 (11.5%) IVT-treated patients, the median NIHSS was 8, and the median DNT was 40 (26.25-56) minutes. In 2018, 72 patients (18.1%) were treated with IVT, median NIHSS was 6 (3–10.25) and the median DNT was 36 (27.25-54.75) minutes. This represented a 56.9% increase in the number of patients thrombolyzed compared to 2017 ($p = 0.009$), with a non-significant decrease in DNT of about 4.5%. When comparing EVT, in 2017, 11 patients (2.8%) received EVT, which increased to 19 (4.8%) in 2018. The mean CT-to-groin puncture time was 174 ± 80.5 min versus 145 ± 28 min (based on data from 17 patients) in 2018, a 16.7% decrease compared to 2017 ($p = 0.29$).

In the EVT group, a good functional outcome (mRS 0–2) was achieved by 6 versus 11 patients in 2018 ($p=1$). In 2017, 2 patients achieved an excellent outcome (mRS 0–1), compared to 7 patients in 2018 ($p=0.55$). When examining the mRS shift, there was a trend towards better outcomes in 2018 ($p=0.29$).

4.2. Experience on extending the thrombectomy TW

From February to December 2019, 437 AIS patients were admitted. From the 238 (54.5%) who arrived in the standard (0-6 hours) TW, 92.9% underwent CTA or MRA, 34.5% had LVO and 30 (12.6%) had EVT; Of these, 11 patients (11.6%) had mRS ≤2 at 3 months.

In the extended TW, 199 patients were screened, and with more restrictive imaging criteria, 63.8% underwent CTA or MRA. LVO was diagnosed in 21.1%, and 8 patients (4%) had EVT, while independent functional outcome was achieved in 4 patients. Number needed to screen (NNS) was 8 in the standard and 25 in the extended TW. Basic demographic data was well

balanced between the two groups. NIHSS was more severe in the standard group (median (IQR) NIHSS 6 (4-12) vs 5 (3-8); p = 0.011), where more LVOs were diagnosed (34.5 vs 22.1%; p = 0.0046) and treated (12.6 vs 4%; p = 0.001).
In the treated patients between the two TWs, age was similar, NIHSS was more severe in the standard TW, and the outcome was worse in early patients (median mRS 4 vs 2.5), but neither result was statistically significant because of the low number of patients. Of all LVO strokes, 65.1% were in the standard TW. Similarly, 78.9% of patients eligible for EVT were in the standard TW.

Extending the time window led to an 83.6% rise in emergency clinical screenings, a 57.5% increase in non-invasive angiography, a 26.7% rise in EVT procedures, and a 36.4% improvement in the rate of independent clinical outcomes among treated patients.

4.3. The impact of COVID-19 infection on AIS outcome

Demographic data and medical history

There was no significant difference in baseline demographic data and medical history between the COVID-19 AIS and non-COVID-19 AIS groups, except hypertension was significantly more prevalent in the non-COVID AIS group (65.6% vs. 86.3%, p=0.02).

Stroke characteristics

At admission, the median NIHSS (interquartile range, IQR) for the COVID-19 AIS group tended to be higher (9 (3-13) vs. 4 (2-10); p=0.06). The COVID-19 group had a numerically higher LVO rate (40.6% vs. 27.5%; p=0.21), with a greater proportion of anterior circulation LVOs (92.3% vs. 64.2%). Among the COVID-19 AIS group, LVO was more frequently

observed in patients with COVID-19 pneumonia compared to those without (55.6% vs. 23.1%; p=0.139).
The different stroke etiologies based on TOAST (Trial of Org 10172 in Acute Stroke Treatment) criteria were as follows: Undetermined strokes were more common in the COVID-19 group (43.8% vs. 35.3%). Cardioembolic strokes were similar (34.4% vs. 31.4%). Small vessel disease was less frequent in the COVID-19 group (3.1% vs. 13.7%). Large artery atherosclerosis was more common in the COVID-19 group (18.8% vs. 11.8%). Other determined causes were absent in the COVID-19 group but present in 7.9% of the non-COVID-19 group.

In our study, 31.3% of COVID-19 AIS patients received acute reperfusion therapy (19% IVT, 12.5% EVT), compared to 23.5% in the control group (11.7% IVT, 11.8% EVT). The DNT was longer in the COVID-19 AIS group (83 vs. 54 minutes; p=0.17), as was the DGT (378 vs. 310 minutes; p=0.33).

COVID-19 severity

Based on the WHO COVID-19 disease severity classification, in our COVID-19 cohort, none of the 32 patients had mild disease, 50% (16/32) had moderate, 37.5% (12/32) had severe, and 12.5% (4/32) had critical COVID-19 severity. We assessed clinical characteristics by dichotomizing patients into mild-moderate and severe-critical categories. There was no significant difference in NIHSS at admission between the groups. The number of LVOs was similar in both groups. ICU transfers occurred only in the severe-critical group. Hospitalization duration was slightly longer in the severe-critical group (18 (6.75-33) days vs. 12.50 (7.50-18.75) days; p=0.39). Mortality was moderately higher in the severe-critical group (37.5% (6/16) vs. 12.5% (2/16); p=0.43). Functional state at discharge was significantly worse in the severe-critical group (mRS 4.4 ± 2.1 vs 2.6 ± 2.3; p=0.014).

Hospitalization and outcome

COVID-19 AIS patients had a longer hospitalization duration compared to non-COVID-19 AIS patients (19.4 ± 17.7 days vs. 9.7 ± 7 days; p=0.003, *Figure 2.A*). A higher proportion of COVID-19 AIS patients were admitted to the ICU (12.5% vs. 1.9%; p=0.16). The median discharge mRS was higher in the COVID-19 AIS group, though not statistically significant (4 vs. 2; p=0.052). Significantly fewer COVID-19 AIS patients achieved a favorable functional outcome (mRS≤2) (12/32 vs. 32/51; p=0.02 *Figure 2.B*). In-hospital mortality was significantly higher in the COVID-19 AIS group (31.3% vs. 11.8%; p=0.02, *Figure 2.C*).

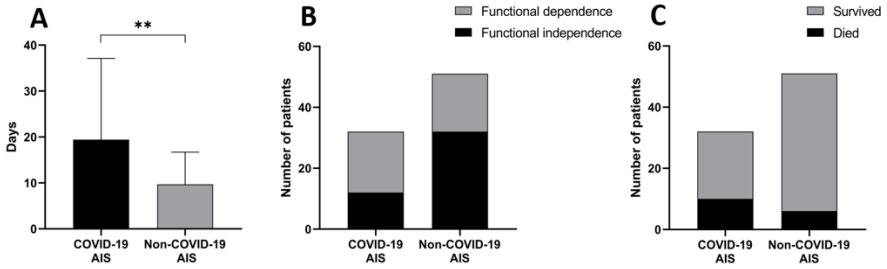

Figure 2. Summarizes the length of hospitalization and outcome results in COVID-19 AIS and non-COVID-19 AIS patients
*(A). The average length of hospitalization. A significant difference in treatment duration can be observed. Data are presented as mean ± SD.**p<0.01. (B). Functional state at discharge. Non-COVID-19 AIS patients showed significantly more favorable functional outcomes (mRS ≤2) than COVID-19 patients; p=0.02 (C). In-hospital mortality rates. There is significantly higher mortality in COVID-19 AIS patients; p=0.02 (45).*

Univariable and multivariable logistic regression analysis

In univariable logistic regression analysis, age (p=0.04), NIHSS (p=0.0007), CRP (p=0.02), and COVID-19 infection (p=0.0339) were all linked to higher mortality. However, in multivariable logistic regression analysis, NIHSS was the only

independent predictor of mortality (p=0.004), while age, CRP, and COVID-19 infection were not.

4.4. Extending the TW for both thrombolysis and thrombectomy

In the one-year study period, 777 confirmed ischaemic stroke patients were admitted to the ED within 24 h of symptom onset: 304 in the 0-4.5 h TW, an additional 82 in the 4.5-6h TW, in the 6-9h TW 149, and in the 9-24h TW 242 more patients were screened. 252 (32.4%) had MRI during working hours (08-20h), while the others had CT-CTA.

Comparing IVT in the standard and extended time window

Age, sex, and NIHSS upon admission were similar between the standard and extended TW groups. A significantly higher proportion of patients received IVT in the standard TW (~39%) compared to the extended TW (~6%). Overall, to find one treatment-eligible patient, 2 had to be screened in the early period (NNS=2), whereas 9 in the late period.

Median (IQR) mRS at 90 days in the IVT group was 3 (1-5) in the standard and 3 (1.75-6) in the extended TW group (p=0.16). Independent clinical outcome (mRS≤2) at 90 days was seen in 49/102 (48.03%) early and 4/14 (28.58%) late-treated patients.

Comparing EVT in the standard and extended time window

There were no differences in sex, initial NIHSS, and LVO rates between patients in the standard and extended TW groups, though patients in the late group were slightly older. IVT was administered before EVT to 27 patients in the early TW and 2 in the late TW. EVT was more common in the standard TW (~9% vs. ~4%), with a higher proportion of LVO patients undergoing thrombectomy in the early TW (~38% vs. ~18%).

Anterior circulation LVOs were predominant in both TWs. The NNS was 10 in the early TW and 24 in the late TW. Baseline clinical characteristics were similar between groups. The recanalization rate (TICI ≥ 2b) was high in both early and late-treated patients (94% vs. 93%), with no significant difference in EVT-related complications. An independent clinical outcome (mRS≤2) at 90 days was observed in 38.4% of early-treated patients and 33.3% of late-treated patients.

Comparing treatment times

We compared treatment times (median (IQR)) between imaging modalities within the same time window and between different TWs using the same imaging modality (MRI).

CT vs. MRI in IVT: Of the 119 IVT patients in the standard TW, 38 (31.9%) had MRI and 81 (68%) had CT. The DNT was slightly longer for MRI compared to CT: 69 (60-87.25) minutes vs. 60 (47-82) minutes (p=0.0405).
Standard vs. extended IVT with MRI: In the MRI thrombolysis group, 38 patients were treated in the standard TW and 13 in the extended TW. The DNT was significantly longer in the extended group: 111 (74-161.5) minutes vs. 69 (60-87.25) minutes (p=0.002).
CT vs. MRI in EVT: Of the 34 thrombectomy patients in the standard TW, 13 (38.2%) had MRI and 21 (61.8%) had CT. DGT was numerically longer for MRI patients compared to CT patients, though not statistically significant: 210 (185-303) minutes vs. 150 (115-220) minutes (p=0.0566).
Standard vs. extended EVT with MRI: The DGT using MRI was similar between the standard and extended TWs: 210 (185-303) minutes vs. 229 (161-241) minutes (p=0.99).

Comparing door-to-imaging times

We compared door-to-imaging times (DIT, median (IQR)) between imaging modalities within the same TW and between different TWs using the same imaging modality (MRI) in treated patients, as well as in all screened patients regardless of whether they eventually received treatment.

CT vs. MRI in treated patients: In the standard TW for IVT-treated patients, DIT was numerically shorter for CT, though not statistically significant: 28.5 (20-49.75) minutes for CT vs. 33.5 (24.5-50.25) minutes for MRI (p=0.28). For EVT-treated patients in the standard TW, DIT was significantly shorter with CT compared to MRI: 20 (15-30) minutes for CT vs. 33.50 (26.75-56.25) minutes for MRI (p=0.002).
CT vs. MRI in all screened patients: Among all patients screened within 24 hours, there was no significant difference in DIT between CT and MRI: 73.50 (34-177) minutes for CT vs. 61.00 (38-125) minutes for MRI (p=0.12). Among patients screened within 4.5 hours, DIT was also not significantly different between CT and MRI: 42 (24-102) minutes for CT vs. 50 (31-88) minutes for MRI (p=0.39).
Standard vs. extended time window in all MRI-screened patients: Among all patients screened with MRI, DIT differed significantly between early and late TWs: 50 (31-88) minutes for the 0-4.5 hour TW vs. 62.5 (37.5-142.8) minutes for the 4.5-9 hour TW (p=0.039). Respectively, 51 (32.5-102.5) minutes for the 0-6 hour TW vs. 80.5 (42.5-160.8) minutes for the 6-24 hour TW (p=0.0022).

5. Conclusions

Keeping up with novel research and implementing new stroke guidelines within existing infrastructure is a significant

challenge. While aiming to improve patient outcomes, the additional workload of identifying eligible patients cannot be overlooked. Our research provides real-world data on key advancements in stroke care in recent years.

Our first study demonstrated that AI-based decision support improved IVT rates, showed a trend towards increased EVTs, and enhanced patient outcomes by streamlining logistics.

Expanding the EVT time window based on advanced imaging led to a 25% increase in EVTs, without a significant difference in clinical outcomes compared to the standard time window.

The COVID-19 pandemic significantly impacted AIS care. While hospitalizations decreased, IVT rates saw only a mild decline, and EVT rates remained stable in Hungary, mirroring global trends. However, COVID-19 was associated with worse clinical outcomes, with COVID-19-infected AIS patients experiencing higher stroke severity, longer hospital stays, worse functional recovery, and increased mortality. The severity of COVID-19 infection further worsened the prognosis, with COVID-19 pneumonia linked to a higher incidence of LVOs, emphasizing the need for multidisciplinary care.

Extending time windows for IVT and EVT meant a 102% increase in patients being screened within 24 hours, resulting in an 11.7% higher IVT rate and a 44% rise in EVTs. MRI proved useful for identifying candidates for extended TW IVT, wake-up strokes, stroke mimics, and complex cases. However, in severe strokes, CT and CTA would be sufficient for EVT eligibility, particularly when IVT is contraindicated.

With the fast-evolving AIS care, further guideline changes are expected. Our four studies highlight the importance of early guideline adoption and technological advancements in refining stroke care pathways. Extending TWs increases access to acute reperfusion therapies, the only current medical intervention for stroke symptom relief. Given the ageing

population and rising stroke burden, stroke care must be efficiently organized to manage clinical and imaging demands. A well-structured system must ensure resilience, adaptability, and optimal care delivery, even during future healthcare crises.

6. Bibliography of the candidate's publications

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