Effectiveness of AI Solution to Analyze CT for Screening Patients with Emergent Large Vessel Occlusion

Non-contrast CT based AI solution for LVO triage and notification

Dong Hoon Shin, MD, Ph.D
CEO of Heuron Co., Ltd.

Brain New Life, Together.

https://iheuron.com

Brain New Life, Together

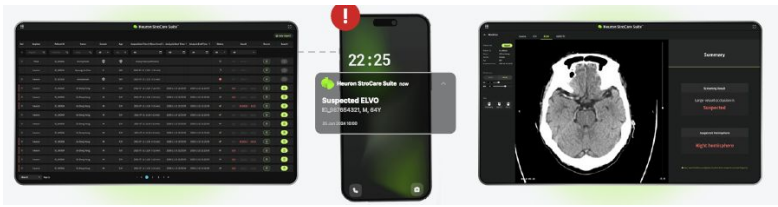
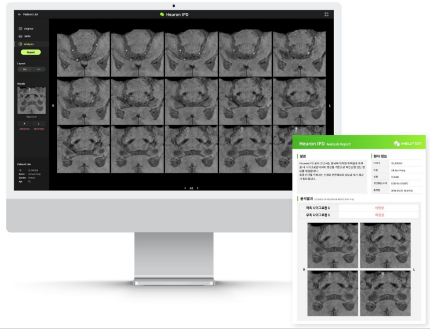
Heuron

We lead in high-barrier neuroscience diagnostics, dedicated to rapidly diagnosing brain diseases through AI technology to uphold the dignity of patients and society.

Heuron's Solution

Heuron's solution reduces barriers to healthcare, addressing everything from acute brain disorders to degenerative neurological conditions.

(as of '24 Q4)

	Neurovascular Disease			Neurodegenerative Disease			
Solution	Heuron StroCare Suite™			Heuron AgingCare Suite™			
Target Disease	Stroke			Parkinson's Disease		Alzheimer Disease	
Modality	CT (Non-contrast)			MRI		MRI/PET-CT	
Analysis	Hemorrhage	Large Vessel Occlusion	ASPECT	Nigrosome1	Neuromelanin	amyloid-ß	Tau
						Glucose	Dopamine
Clinical Value	Aiding in the triage of emergency patients and supporting rapid treatment decisions 			Switching from use of PET-CT scans to MRI for detecting lesions in Parkinson's disease diagnosis 		Analyzing atrophy in brain regions and using longitudinal analysis allows for early dementia diagnosis 	

02

Heuron SCS™

Why stroke?

The problem at hand

Once lost, recovering the brain is incredibly challenging

6.3 hours

The average time consumption from the first abnormal symptom detection to a hospital arrival in South Korea

2nd lethal

Leading cause of death, 6.6 million died globally in 2019

160M DALYs

The sum of years lost due to premature death and years lived with disability in 2021 worldwide

101M aftermath

The number of people living with the stroke aftermath in global

Every second counts!!

Source: 1) South Korea Ministry of Health and Welfare,2018 2) WHO, 2020 3) Institute for Health Metrics and Evaluation GBD 2021 4) World Stroke Organization, 2024

Stroke in Slovakia

12,675
Incidence
In 2021

106,246
Prevalence
In 2021

Estimated increase 2015-2035

- Incidence 53%
- Prevalence 36%
- Dealths 77%
- DALYs Lost 52%

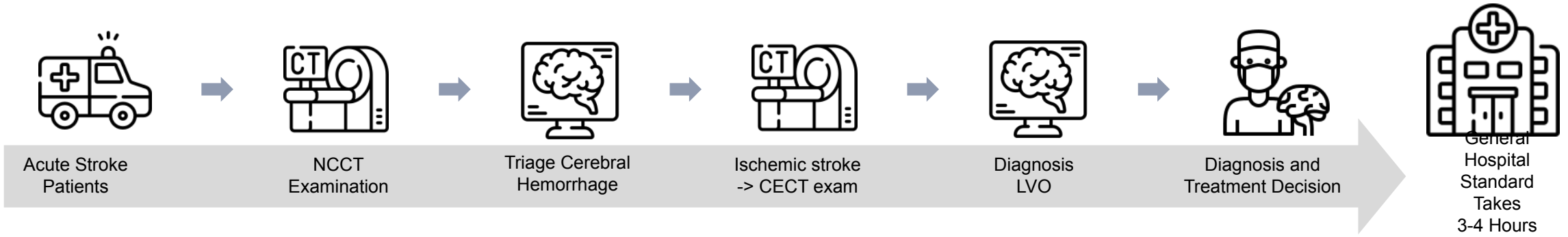
Risk factors and mortality rates of Slovakia and EU average

Source : 1) Institute for Health Metrics and Evaluation GBD 2021 2) The Burden of Stroke in Europe report conducted by King's College London for the Stroke Alliance for Europe

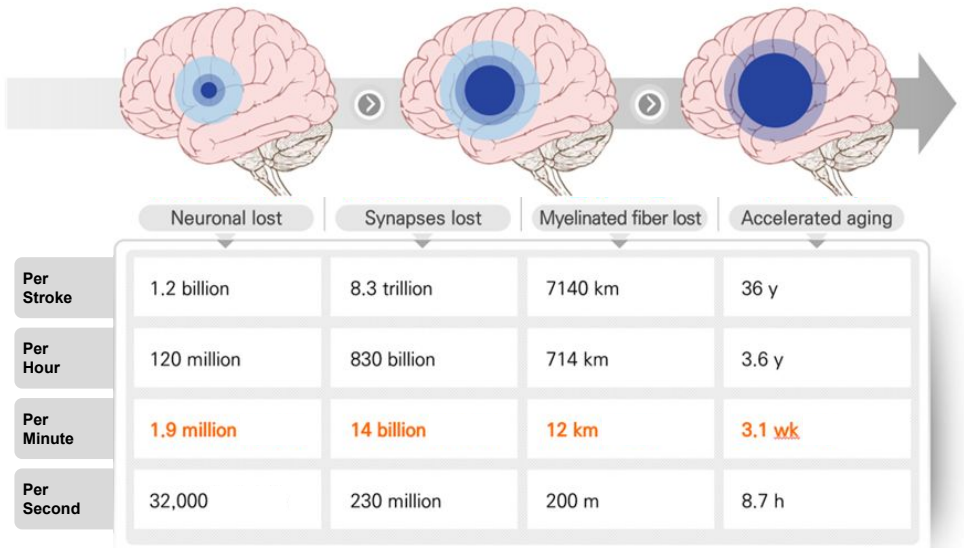
Time is Brain

Stroke Treatment 'Golden Hour'

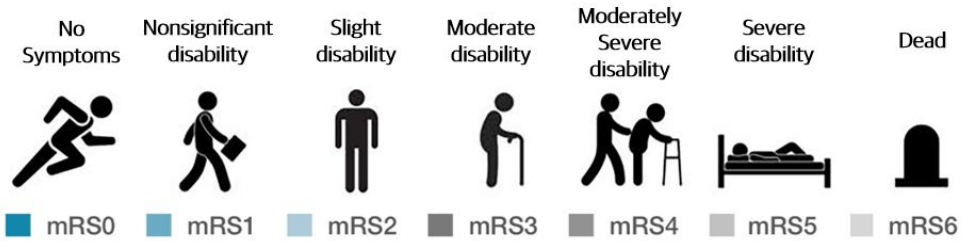
Consultation and Treatment Procedures for Acute Stroke Patients



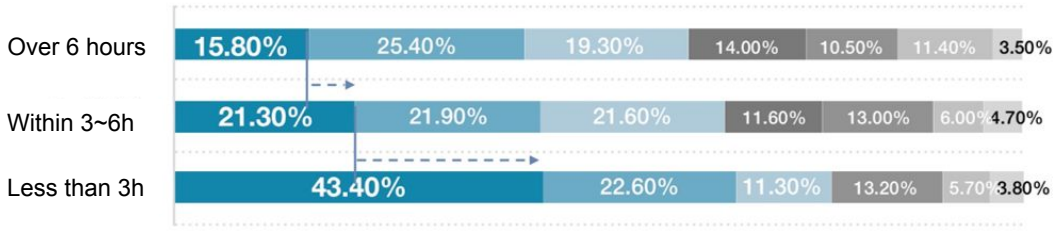
Brain Damage and Prognosis According to the Time Elapsed After Acute Stroke Onset



	Neuronal lost	Synapses lost	Myelinated fiber lost	Accelerated aging
Per Stroke	1.2 billion	8.3 trillion	7140 km	36 y
Per Hour	120 million	830 billion	714 km	3.6 y
Per Minute	1.9 million	14 billion	12 km	3.1 wk
Per Second	32,000	230 million	200 m	8.7 h



**mRS(modified Rankin Scale): To measure the degree of disability in patients who have had a stroke*



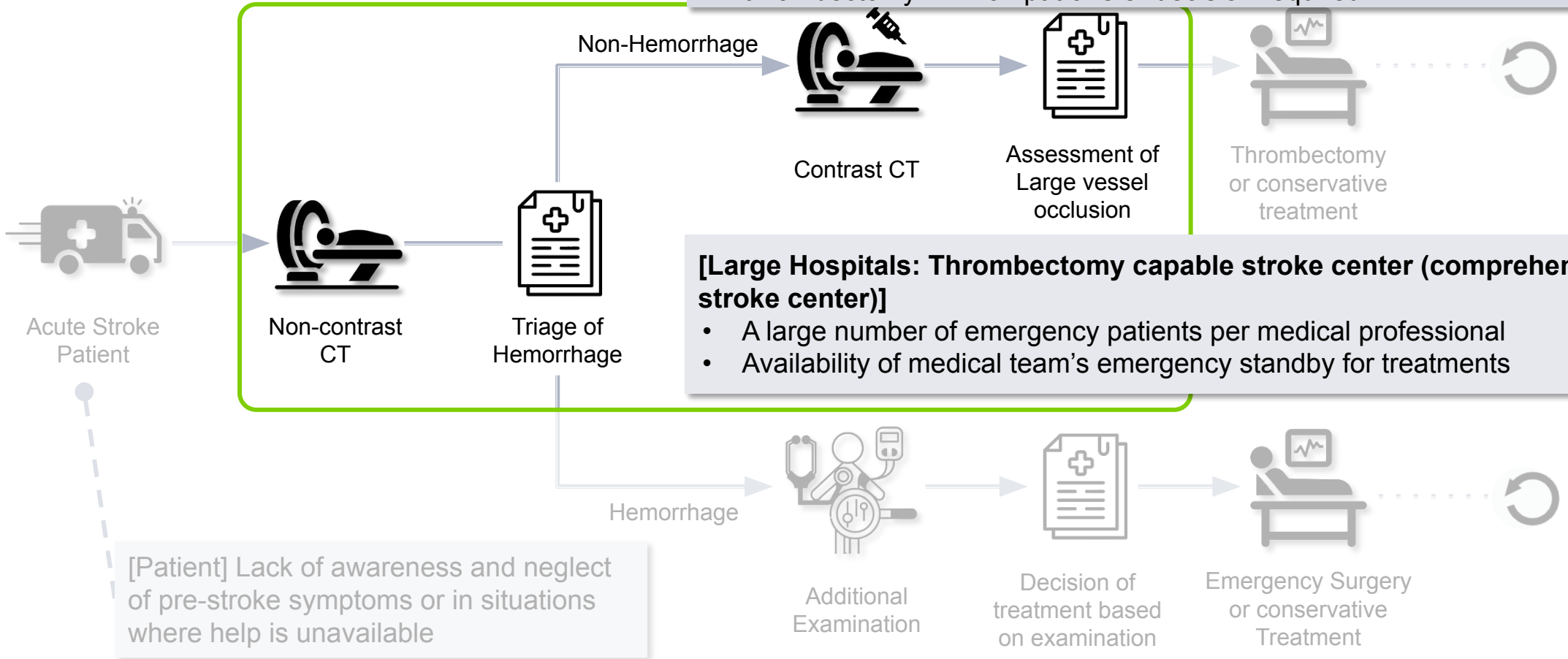
(Source: Fenyang Meng Korean J Radiol 2023;24(11):1046-1048/ Saver et al., Stroke 2006;37:263-266/ Korea Severance Hospital, Neurology-Neuro surgery-Psychiatry Journal 2018, Korean J Radiol 2023;24(11):1049-1051)

Key Time-Consuming Challenges in Stroke Centers

Solutions for Reducing Time-Consuming Points

[Small- and Medium-sized Hospitals: Primary Stroke Center]

- Absence of stroke imaging specialists
- Insufficient infrastructure for stroke treatments, such as mechanical thrombectomy → Prompt transfer decision required



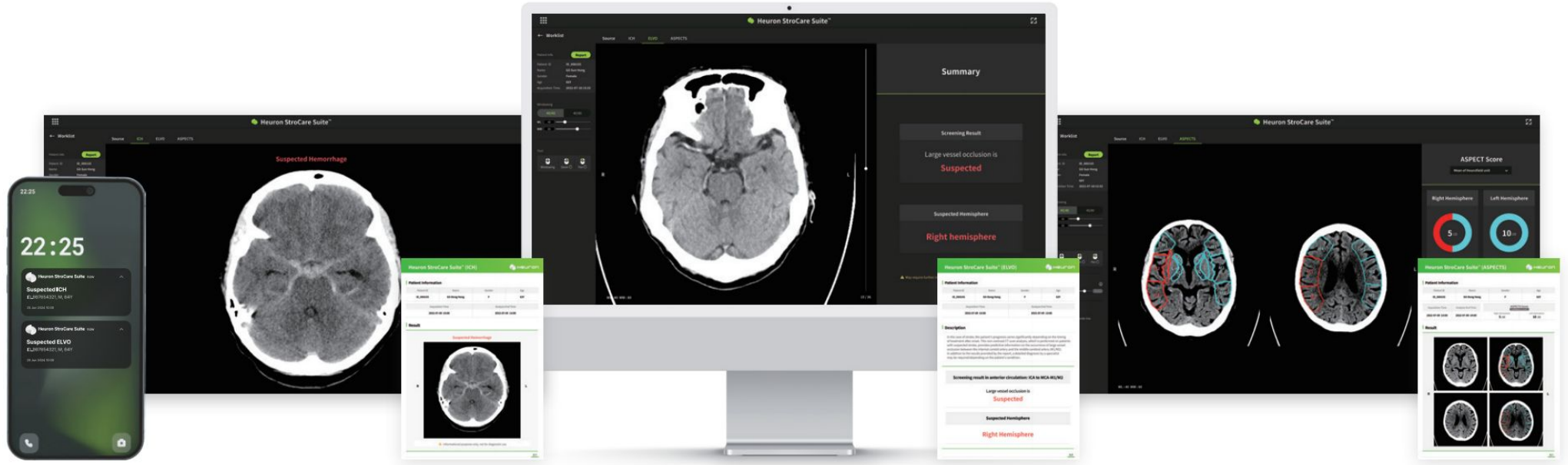
[Large Hospitals: Thrombectomy capable stroke center (comprehensive stroke center)]

- A large number of emergency patients per medical professional
- Availability of medical team's emergency standby for treatments

[Patient] Lack of awareness and neglect of pre-stroke symptoms or in situations where help is unavailable

Heuron StroCare Suite™

Rapid Notification for Stroke Patient Treatment



Heuron ICH **Heuron ELVO** **Heuron ASPECTS**

FDA 510(k) cleared

Heuron StroCare Suite™

MMS/어플리케이션을 통한 응급 환자 분석 결과 및 알람 시스템

Notification

Get immediate notifies on critical findings

Worklist

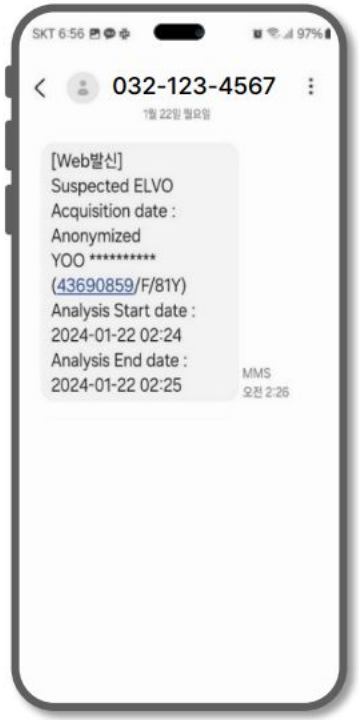
Can access real-time worklist & patient transfer in/out tagging

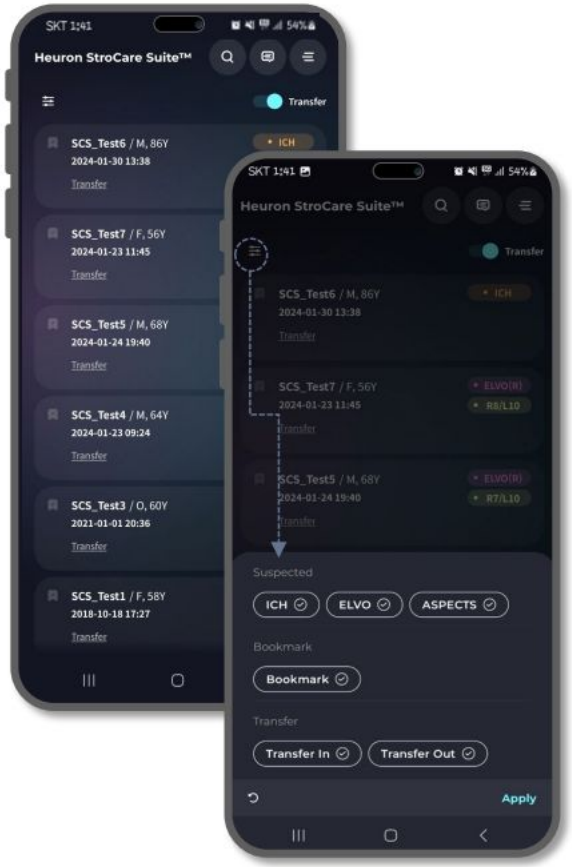
Viewer

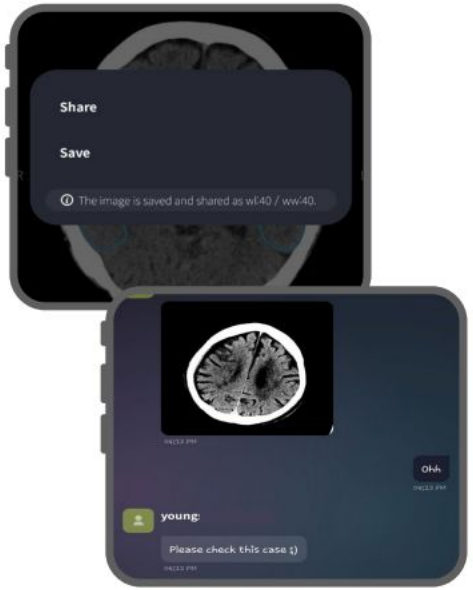
Can easily switch original and result images in the viewer

Share/ Save/ Message

Can share or save images & closed network message function







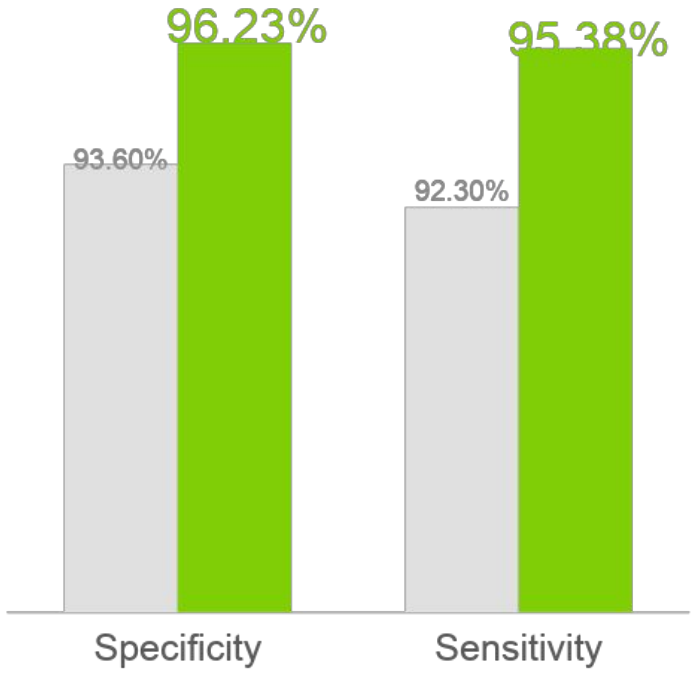
Heuron ICH

Training Dataset & Clinical Trial for MFDS clearance

	Training Data-set		
	Total	Positive cases of hemorrhage	Negative cases of hemorrhage
Patient-wise	21,816	8,920	12,896
Slice-wise	749,590	107,454	642,136

Clinical Test Data-set (patient-wise)		
Total	Positive cases of hemorrhage	Negative cases of hemorrhage
236	106	130

- Study design: Open Label, Single-center, Retrospective, Pivotal Trial
- Reference Standard:
  Two neurologists reviewed blinded brain CT images and established a reference standard based on the hemorrhagic stroke diagnostic criteria
  - Presence of hemorrhagic stroke
    Subtypes of hemorrhagic stroke, if diagnosed with (intracerebral, intraventricular, subarachnoid, epidural, subdural)
    The number of CT slices where hemorrhage is confirmed, if diagnosed with

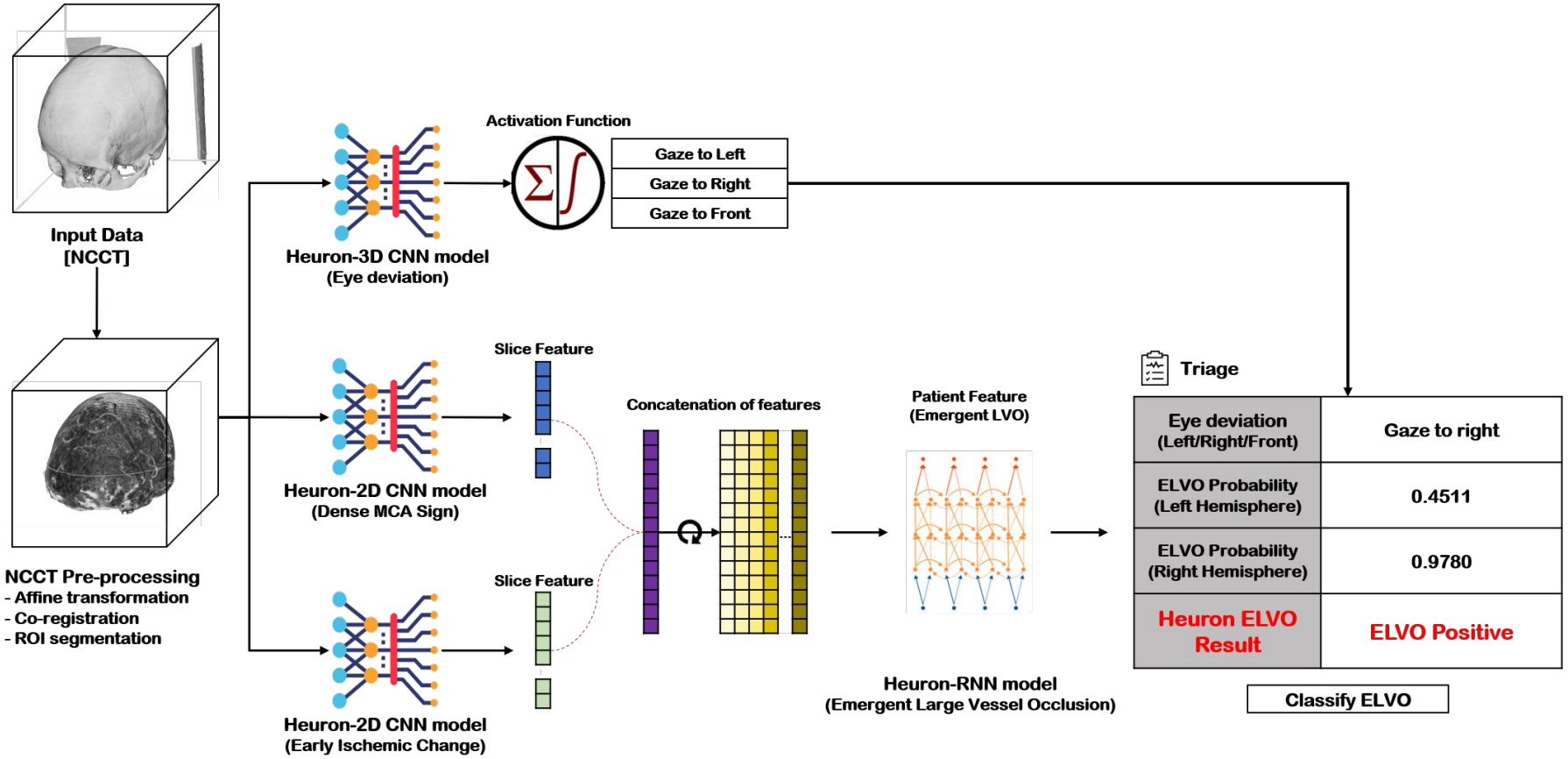


- Primary Endpoint:
  Heuron ICH: Sensitivity & Specificity
  - PPV: 94.4%
  - NPV: 96.87%
  - Accuracy : 95.76%

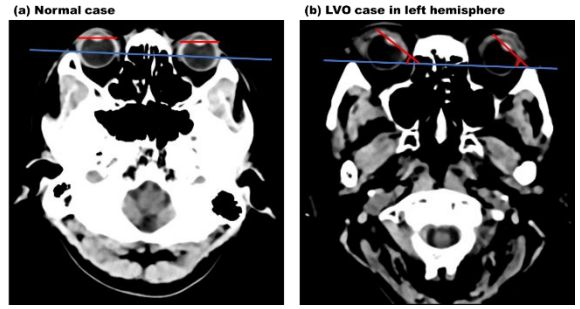
Heuron ELVO

LVO prediction model structure

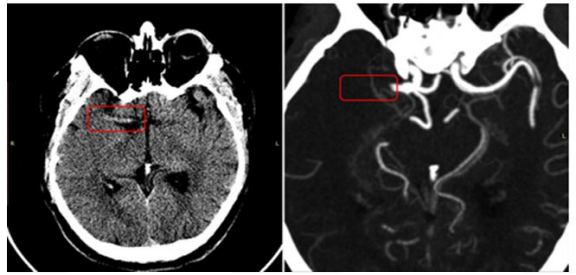
Prediction of acute LVO patients on NCCT
Based on three image-biomarkers



- Eyeball deviation

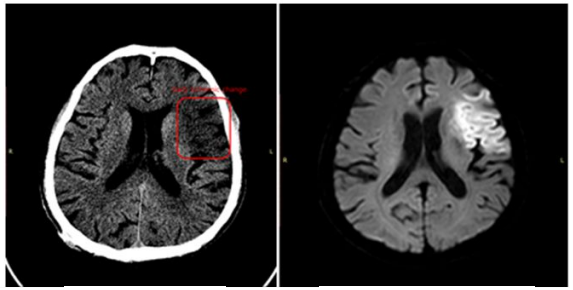


- Dense MCA sign



[NCCT] [CTA]

- Early ischemic change



[NCCT] [DWI]

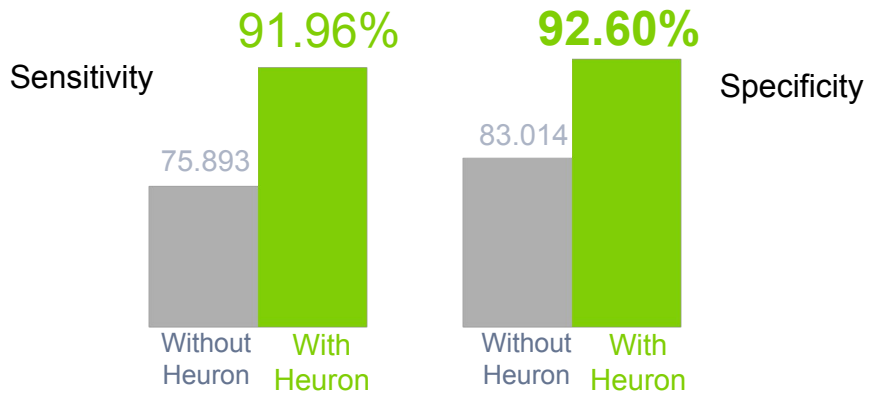
Heuron ELVO

Clinical Trial for MFDS clearance

Clinical Trial for MFDS clearance – A Pivotal clinical trial in single center

Clinical Data-set (Patient-wise)		
Total	Positive cases of LVO*	Negative cases of LVO
477	112	365

- Study design: Open Label, Single-center, Retrospective, Pivotal Trial
- Total 477 cases (Positive ELVO cases: 112, Negative cases: 365)
- Reference standard: Two stroke experts provided reference standard using medical records with diagnosed code
- Primary Endpoint: Statistical difference in sensitivity and specificity when only visual interpretation of non-contrast CT and when referring to AI analysis results



ELVO classification	Sensitivity % (TP/TP+FN) [95% CI]	Specificity % (TN/TN+FP) [95% CI]	AUROC [95% CI]
Standalone	88.4 (99/112) [81.0–93.7]	91.2 (333/365) [87.9–93.9]	0.93 [0.90–0.96]

	Sensitivity (TP/TP+FN)			Specificity (TN/TN+FP)			AUROC		
Consensus level analysis	Unassisted stage	AI-assisted stage	p value	Unassisted stage	AI-assisted stage	p value	Unassisted stage	AI-assisted stage	p value
%, [95% CI]	75.9 (85/112), [66.9–83.7]	92.0 (103/112), [85.3–96.3]	0.0009	83.0 (303/365), [78.8–86.7]	92.6 (338/365), [89.4–95.1]	<0.0001	0.87,† [0.83–0.90]	0.95,† [0.92–0.97]	0.04
Individual level analysis %, [95% CI]									
Reader 1	68.8 (77/112), [59.3–77.2]	90.2 (101/112), [83.1–95.0]	<0.0001	85.5 (312/365), [81.4–88.9]	92.1 (336/365), [88.8–94.6]	0.002	0.84,† [0.79–0.88]	0.96,† [0.94–0.98]	0.02
Reader 2	58.0 (65/112), [48.3–67.3]	81.3 (91/112), [72.8–88.0]	<0.0001	89.86 (328/365), [86.3–92.8]	93.97 (343/365), [91.0–96.2]	0.04	0.83,† [0.78–0.87]	0.95,† [0.92–0.97]	0.02
Reader 3	85.7 (96/112), [77.8–91.6]	79.5 (89/112), [70.8–86.5]	0.26	46.6 (170/365), [41.4–51.8]	92.9 (339/365), [89.7–95.3]	<0.0001	0.82,† [0.78–0.86]	0.91,† [0.86–0.94]	0.11
Reader 4	57.1 (64/112), [47.5–66.5]	74.1 (83/112), [65.0–81.9]	0.0009	66.9 (244/365), [61.8–71.7]	90.7 (331/365), [87.2–93.5]	< 0.0001	0.78,† [0.73–0.83]	0.92,† [0.88–0.94]	0.02

Interrater reliability of agreement		
Fleiss' kappa	**Unassisted stage**	**AI-assisted stage**
κ [95% CI]	**0.27 [0.26–0.28]**	**0.75 [0.74–0.76]**

Performance of ASPECTS scoring system in ER

J NeuroIntervent Surg

Objective

To develop and validate an automated ASPECTS scoring system using deep learning algorithm.

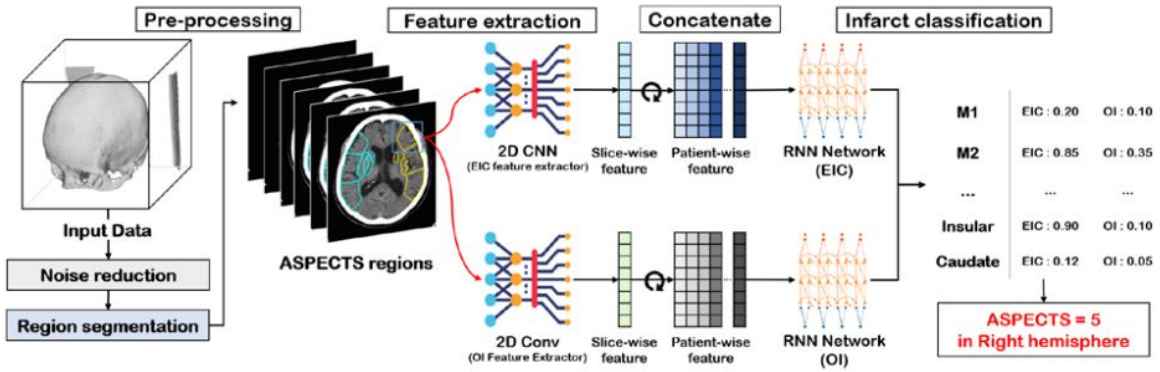
Validation dataset

- Randomized data selection was performed in patients aged ≥19 years with thrombolysis code activation in ER
- final diagnosis of AIS was confirmed using diffusion-weighted MRI
- NCCT slice thickness varied from 3 to 5 mm

ASPECTS reference standard with NCCT

2 experts with ≥ 10 years of clinical experience

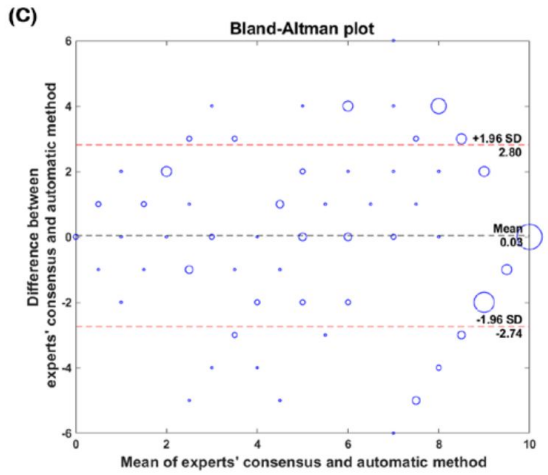
(if the results were different, it determined by consensus between the 2 experts)

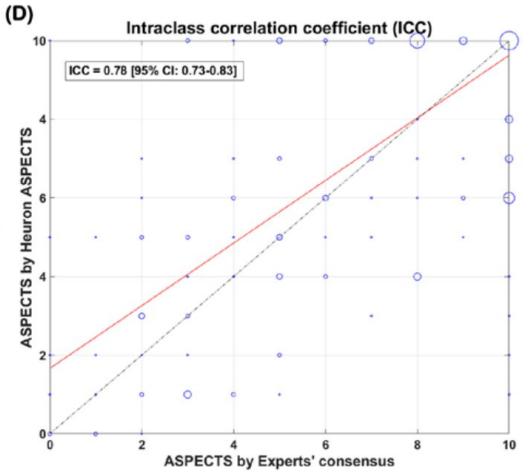


In conclusion,

Heuron ASPECTS effectively measured ASPECTS in patients with suspected ischemic stroke on NCCT scans and suggesting the potential usefulness of DL algorithm software in aiding physicians in stroke patient care.

Performance of Heuron ASPECTS, which was the degree of agreement with the reference standard





Consensus vs. cASPECTS

Mean diff. < *0.35* = **0.032**

ICC **0.78**

Good-to-Excellent Agreement

- Lee S-J, et al. J NeuroIntervent Surg 2023;0:1–7. doi:10.1136/jnis-2022-019970

Heuron SCS

External Validation: multi-center study

External Validation – more than 6 institutions (4 different vendors' CT scanner included)

Validation data-set (Patient-wise)			
Total	Positive cases of ICH	Positive cases of LVO*	Negative cases of ICH or LVO*
2,808	973	502	1,333

**Proximal anterior circulation only – ICA to MCA-M1/M2 bifurcation*

Heuron ICH performance

	GT-ICH positive	GT-ICH negative
ICH positive Prediction	925	19
ICH negative Prediction	48	1,816

- **Sensitivity: 95.07% [95% CI: 93.51 to 96.34%]**
- **Specificity: 98.96% [95% CI: 98.39 to 99.38%]**
- Positive prediction value: 97.99% [95% CI: 96.89 to 98.70%]
- Negative prediction value: 97.42% [95% CI: 96.63 to 98.03%]
- **Accuracy: 97.61% [95% CI: 96.98 to 98.15%]**

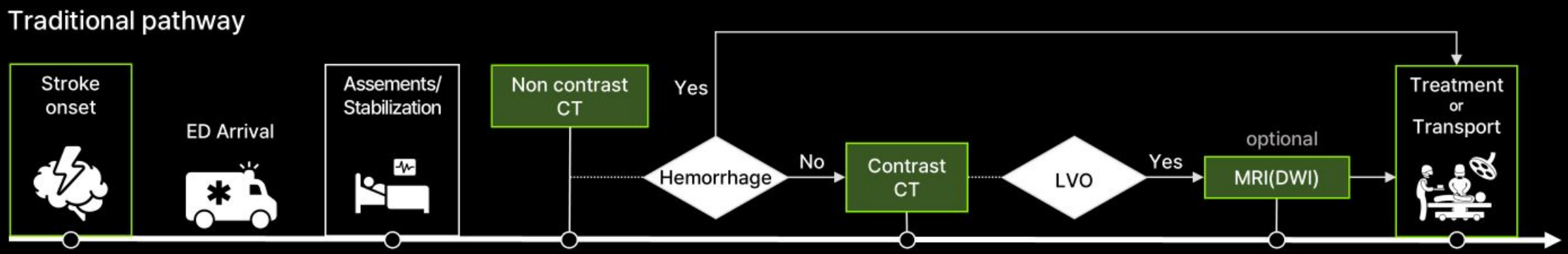
Heuron ELVO performance

	GT-LVO positive	GT-LVO negative
LVO positive Prediction	411	137
LVO negative Prediction	93	2,167

- **Sensitivity: 81.55% [95% CI: 77.88 to 84.84%]**
- **Specificity: 94.05% [95% CI: 93.01 to 94.98%]**
- Positive prediction value: 75.00% [95% CI: 71.73 to 78.01%]
- Negative prediction value: 95.88% [95% CI: 95.10 to 96.55%]
- **Accuracy: 91.81% [95% CI: 90.73 to 92.80%]**

Heuron StroCare Suite™ : Faster triage, prompt actions

Reduce treatment initiation time with shorter process



Heuron StroCare Suite™ : Proven and market ready

First FDA-Approved Korean AI solution for triage and notification

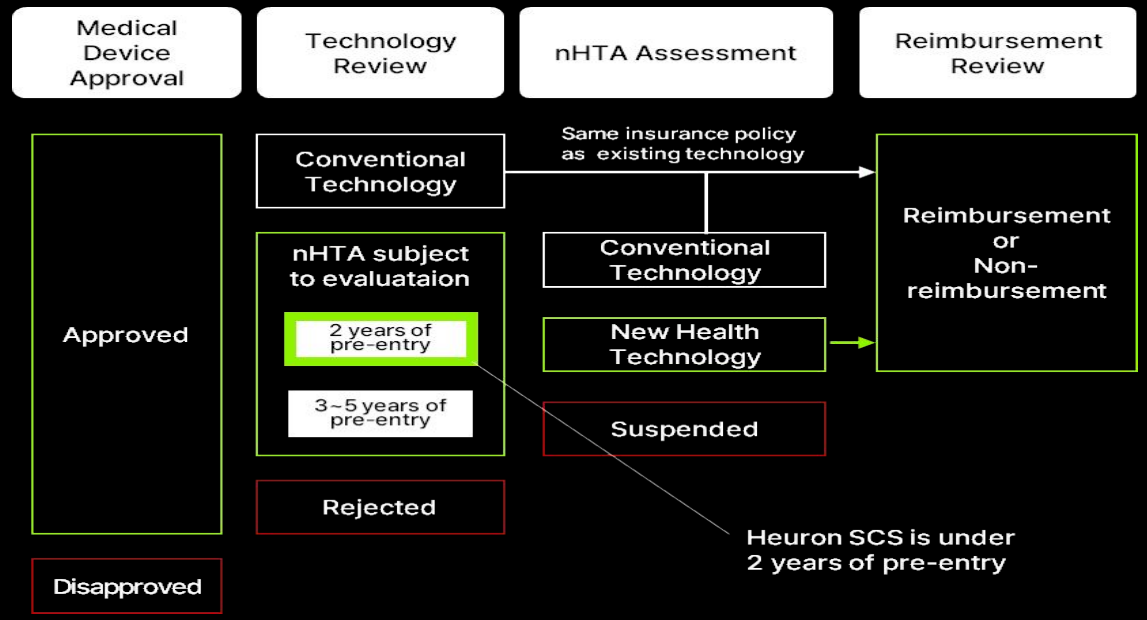
Heuron ICH – FDA 510(K) Cleared

Detects and triages suspected hemorrhages to prioritize emergency patients.

Mass General Brigham

Designated by the Korean MOH as an innovative medical technology

Heuron StroCare Suite is currently in the pre-entry phase under the nHTA* track. New Health Technology Assessment System



03

Clinical Application

Real-World Evidence

Previous publication in LVO triage based on AI solution

Cerebrovasc Dis Extra, 2022 – Brainomix e-Stroke Suite (CTA)

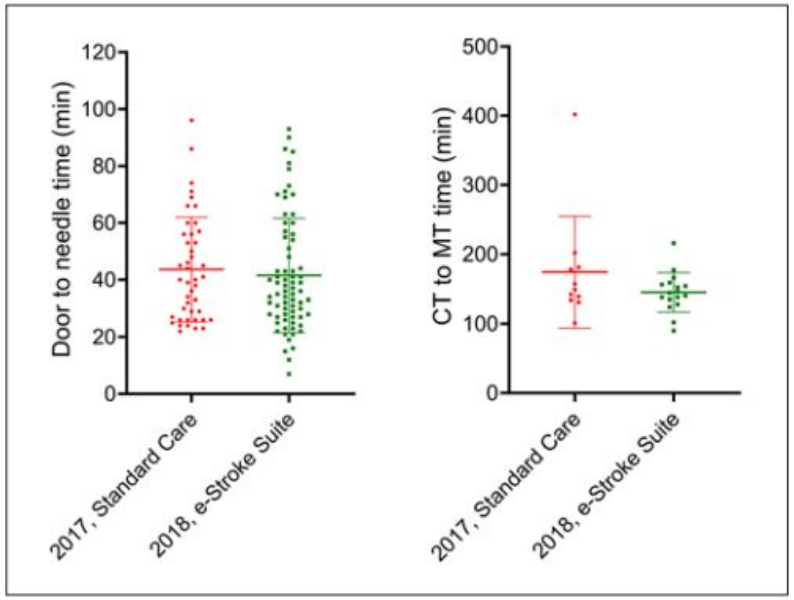


Fig. 1. Treatment times for patients in consecutive years for thrombolysis (left) and MT (right).

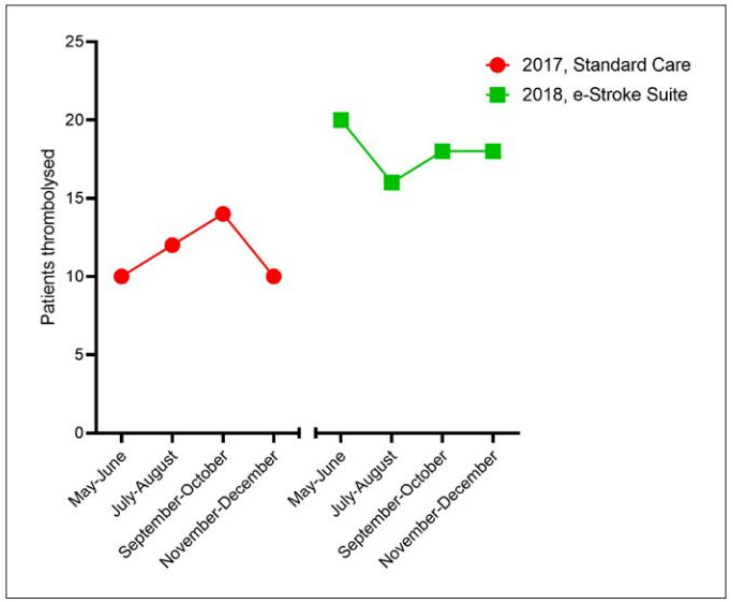


Fig. 2. Thrombolysis treatment rates over 2-month periods during 2017 and 2018.

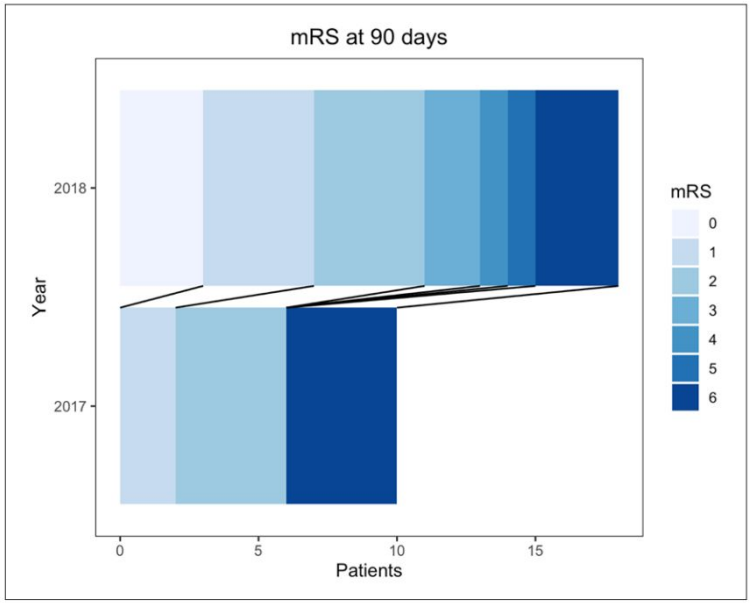


Fig. 3. mRS distributions at 90 days following stroke in the MT cohort.

- **Data was collected for 7 months in 2017 and 2018 to compare the effects before and after utilizing AI solutions.**
- **CT-to-groin puncture time decreased by 16% from 174±80.5 minutes in 2017 to 145±28 minutes in 2018.**
- **The number of cases in which mechanical thrombectomy was performed increased from 11 cases in 2017 to 19 cases in 2018.**
- **The number of patients with an mRS score (at 90 days) of '0' increased from 2 (18%) cases in 2017 to 7 (37%) cases in 2018.**

Previous publication in LVO triage based on AI solution

JAMA Neurology, 2023 – Viz.ai CTA

JAMA Neurology | Original Investigation

Automated Large Vessel Occlusion Detection Software and Thrombectomy Treatment Times

A Cluster Randomized Clinical Trial

Juan Carlos Martinez-Gutierrez, MD; Youngran Kim, PhD; Sergio Salazar-Marioni, MD; Muhammad Bilal Tariq, MD; Rania Abdelkhaleq, MPH; Arash Niktabe, DO; Anjan N. Ballekere, MS; Ananya S. Iyyangar, BS; Mai Le, BS; Hussain Azeem, BS; Charles C. Miller, PhD; Jon E. Tyson, MD, MPH; Sandi Shaw, RN; Peri Smith, RN; Mallory Cowan, RN; Isabel Gonzales, RN; Louise D. McCullough, MD, PhD; Andrew D. Barreto, MD; Luca Giancardo, PhD; Sunil A. Sheth, MD

Table 1. Patient Demographics

Characteristic	Total cohort (n = 243), No. (%)	Pre-AI (n = 140), No. (%)	Post-AI (n = 103), No. (%)	*P* value
Age, y, median (IQR)	70 (58-79)	69.5 (58.5-78)	71 (57-79)	.68
Sex				
Female	122 (50)	73 (52)	49 (48)	.48
Male	121 (50)	67 (48)	54 (52)	
Last known well to hospital arrival, min, median (IQR)	132 (61-498)	131.5 (61-472)	147 (65-569)	.60
NIHSS score	17 (11-22)	17 (11-23)	16 (11-21)	.19
RACE score ≥5	187 (77)	110 (79)	77 (75)	.49
CT ASPECTS	9 (7-10)	9 (7-10)	10 (8-10)	.04
IV tPA	111 (46)	63 (45)	48 (47)	.80
Occlusion location				
Internal carotid artery	42 (17)	29 (21)	13 (13)	.11
M1 middle cerebral artery	111 (46)	56 (40)	55 (53)	
M2 middle cerebral artery	51 (21)	29 (21)	22 (21)	
Basilar artery	11 (5)	9 (6)	2 (2)	
Cervical internal carotid artery and tandem intracranial	9 (4)	4 (3)	5 (5)	
Posterior cerebral artery	5 (2)	2 (1)	3 (3)	
Vertebral artery	3 (1)	3 (2)	0 (0)	
Other	11 (5)	8 (6)	3 (3)	

Table 2. Clinical Outcomes and Time Metrics

Characteristic	Total cohort (n = 243), No. (%)	Pre-AI (n = 140), No. (%)	Post-AI (n = 103), No. (%)	*P* value
DTG time, min (IQR)	97 (75-113)	100 (81-116)	88 (65-110)	.002
Hospital arrival to IV tPA bolus time, min (IQR)	30 (21-41)	30 (22-44)	28 (21-36)	.14
Initiation of CT scan to EVT start time, min (IQR)	80 (60-96)	85 (68-99)	72 (55-90)	<.001
Length of stay, d (IQR)	7 (4-11)	7 (4-12)	6 (3-10)	.11
TICI 2b/3 reperfusion	219 (90)	124 (89)	95 (92)	.34
Safety outcomes				
Symptomatic ICH	9 (4)	7 (5)	2 (2)	.21
Any ICH	43 (18)	24 (17)	19 (18)	.81
Mortality	57 (23)	44 (31)	13 (13)	<.001

Abbreviations: AI, artificial intelligence; CT, computed tomography; DTG, door to groin; EVT, endovascular stroke therapy; ICH, intracerebral hemorrhage; IV tPA, intravenous tissue plasminogen activator; TICI, thrombolysis in cerebral infarction.

Table 3. Mixed-Model Stepped-Wedge Outcomes[a]

Characteristic	Coefficient (95% CI)	*P* value
Primary outcome		
DTG time, min	−11.2 (−18.22 to −4.2)	<.01
Secondary outcomes		
Initiation of CT scan to EVT start time, min	−9.8 (−16.9 to −2.6)	<.01
Hospital arrival to IV tPA bolus time, min	−3.5 (−9.1 to 2.2)	.23
Length of stay, d	−0.4 (−2.6 to 1.7)	.72

Abbrevations: CT, computed tomography; DTG, door to groin; EVT, endovascular stroke therapy; IV tPA, intravenous tissue plasminogen activator.

[a] Regressions adjusted for age, sex, and National Institutes of Health Stroke Scale score.

Significantly reduced metrics

- Door-to-groin (DTG) time: 11.2 mins↓
- CT-to-EVT time: 9.8 mins ↓

□ Ratio of mortality reduced significantly

Reduction Treatment Time for Stroke Patients in ER

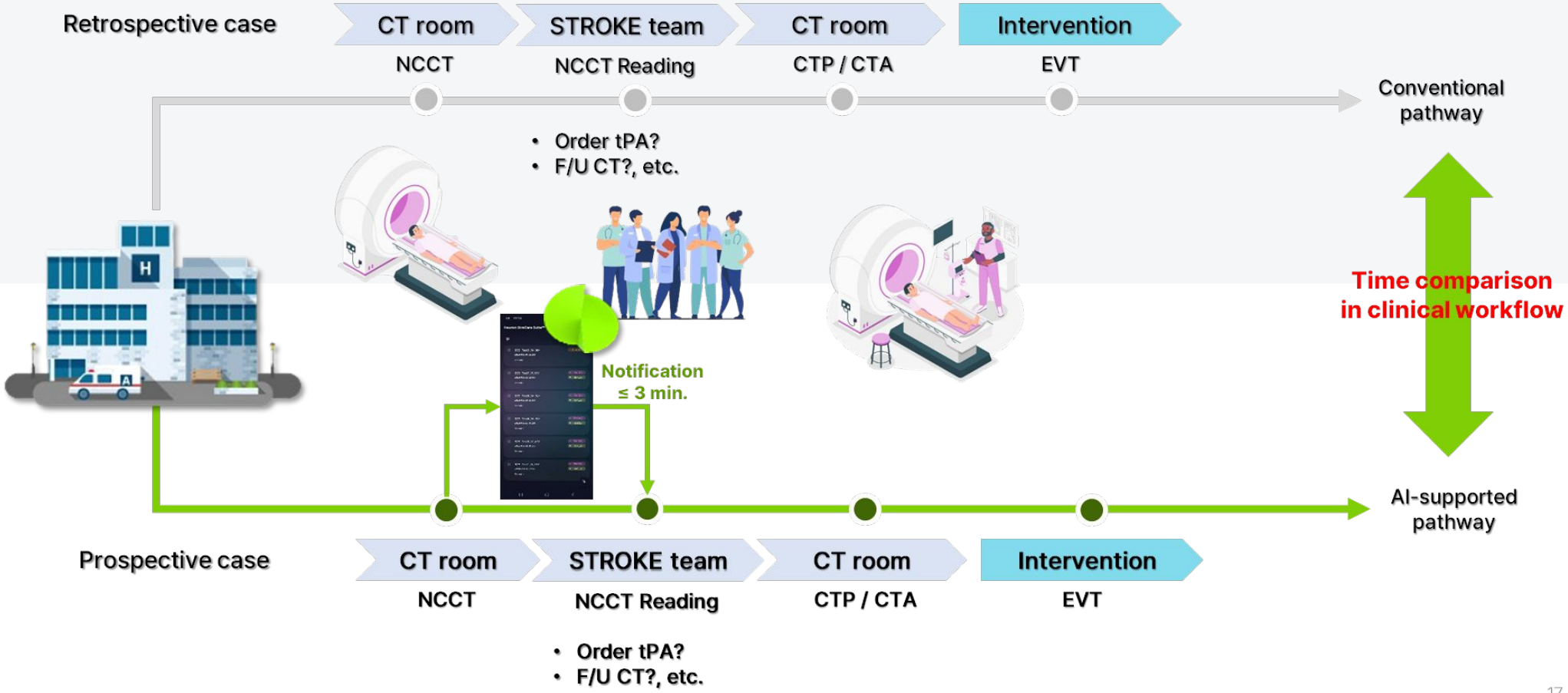
Retrospective & Prospective observation study in single thrombectomy capable stroke center

Objective

To compare whether the treatment time could be reduced when an AI supporting system was used

Study design

Single-center, retrospective-prospective observational study



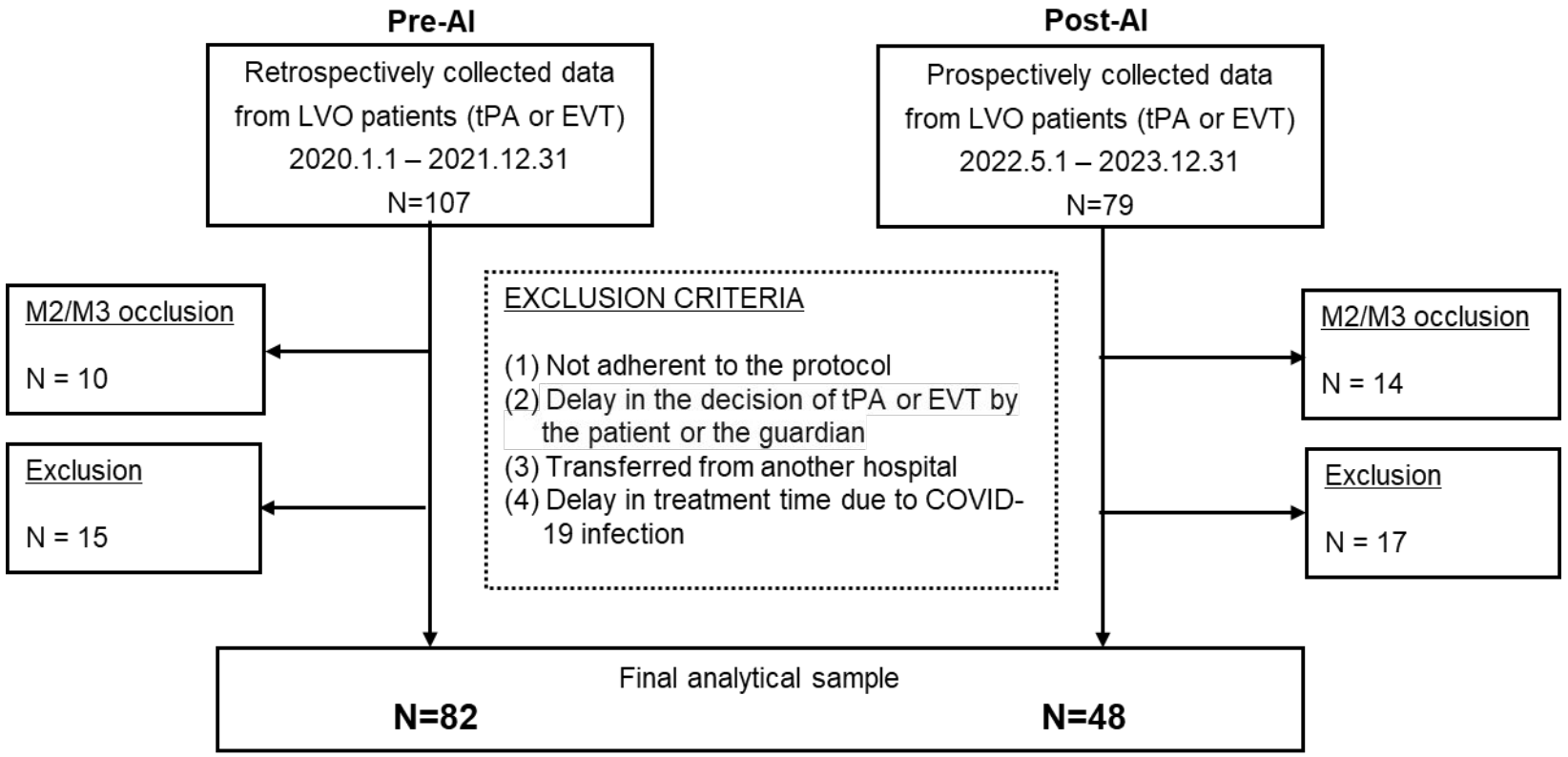
Lim et al., J Clin Med, 2025

Flowchart of study
Inclusion criteria

(1) Aged > 19

(2) Patients suspected of stroke who visited the emergency room and finally diagnosed with acute stroke.

(3) Performed Mechanical Thrombectomy or receiving tPA (tissue Plasminogen Activator).



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Clinical Application

Primary endpoint

Heuron ELVO

CT-to-Notification time

Suspected Stroke Patients

NCCT Test

Stroke Team (ST) Care

Angio/Perfusion Test

IVT

EVT

ER Door to CT Time

CT to ST initial care Time

CT to IVT Time

CT to EVT Time

ER Door to IVT Time

ER Door to EVT Time

ER Admission

NCCT Scan Time

Time on stroke team initial care

tPA Start

Arriving at the OR

Clinical Application - Results

Total cases [Pre-AI (RS): 82 cases, Post-AI (PS): 48 cases]

Outcomes	Coefficient	(95% CI)	p-value
Primary outcomes:			
Door to intervention (minutes)			
Door to IV tPA	-8.9	(-18 to 0.2)	0.058
Door to EVT	-30.2	(-56.1 to -4.3)	0.025
Secondary outcomes:			
- Detailed treatment time (minutes)			
CT scan to NR	-16.4	(-27.6 to -5.3)	0.005
CT scan to intervention			
CT scan to IV tPA	-6.4	(-13.2 to 0.5)	0.072
CT scan to EVT	-29.3	(-53.6 to -5)	0.02
- Changes in scores from initial status (scores)			
ΔNIHSS (discharge – presentation)	-4.3	(-8.3 to -0.2)	0.044
ΔmRS (discharge – presentation)	0	(-0.6 to 0.6)	0.952
ΔmRS (3-month follow-up – presentation)	-0.2	(-0.9 to 0.5)	0.645

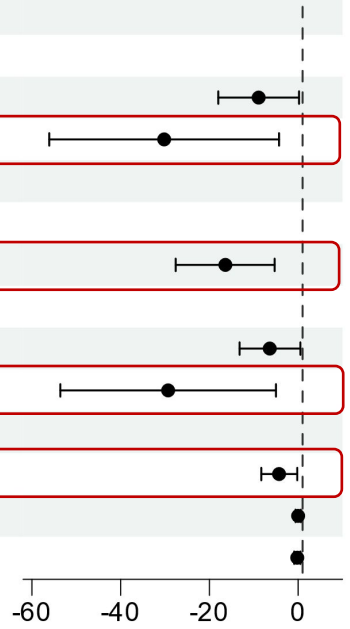

Figure 1. Estimated coefficients of the use of the AI-based stroke detection system using a multivariate linear regression model

Adjustments were made for age (10-year increments), sex, the number of comorbidities, NIHSS at presentation, and clot location.

Abbreviations: CI, Confidence Intervals; CT, Computed Tomography; NR, Neurologist consultation; tPA, tissue Plasminogen Activator; EVT, Endovascular Therapy; NIHSS, National Institutes of Health Stroke Scale; mRS, modified Rankin Scale.

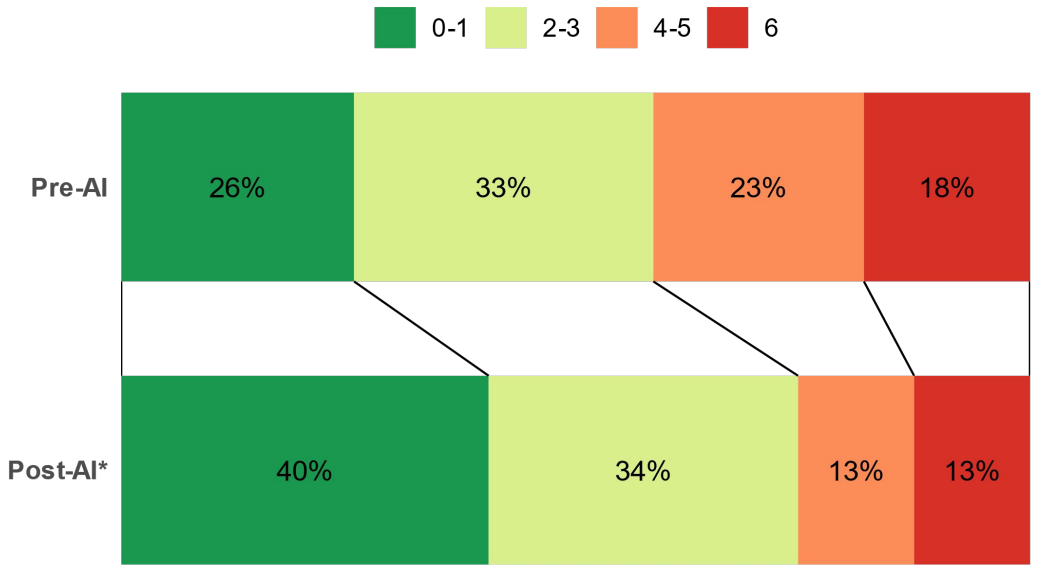

Figure S2. Percentages (%) of mRS at 3-month follow-up

* One participant in the post-AI cohort was excluded in this figure due to missing information for the mRS score at the 3-month follow-up.

Conclusion

- After utilizing the AI solution, the time from CT imaging to the stroke team's initial care and to IVT or EVT were reduced compared to before the application.
- In EVT case, good outcome which was checked 3 months after EVT (mRS 3-months) were increased ratiometrically in the AI supported group.
- Further large-scale evaluation will be needed in multiple-centers.
- Although confirmation through additional validation is required, Heuron StroCare Suite™ - ELVO will be a useful tool for clinicians to make fast decision, especially, it will be valuable in remote regions where clinical expert may be limited.

THANK YOU

https://iheuron.com