



The Study Protocol LVO detection CTA has been updated as of September 2, 2021 based on feedback provided by vendors and clinical institutes on v1.0. Changes have been made in articles 3.1 and 5.1-5.3.

Earlier versions remain available in the archive on www.AlforRadiology.com/project-air.

Study Protocol

LVO detection on CTA in stroke

as part of Project AIR

1. Objective

Validate and compare the stand-alone diagnostic performance of commercial artificial intelligence (AI) based software for the automated detection of large vessel occlusions (LVO) on computer tomography angiography (CTA) in patients with a suspicion of acute ischemic stroke.

2. Study design

An ongoing retrospective study in which commercial AI software is being validated on a dataset from multiple centers. Vendors make their algorithm temporarily available to the researchers to generate the results. The data will not be shared with the vendors. Reader studies on the same dataset are performed by radiologists to provide context to the stand-alone software performance.

3. Study population

3.1. Inclusion criteria

- Centers: Academic, non-academic
- Patient age: >18 years old
- Patients with a suspicion of acute ischemic stroke
- Maximum one study per subject
- CTA acquired from 2017 and onwards
- CTA available within 24 hours after onset or last seen well
- CTA slice thickness <2mm
- Non contrast CT available
- Occlusions:
 - Full occlusion in middle cerebral artery (M1, M2 stop) or intracranial internal carotid artery.
- Controls:
 - CTA without occlusion or significant stenosis (70%)

3.2. Exclusion criteria

- CTA trauma
- Intracranial hemorrhage



- Occlusion types other than middle cerebral artery (M1, M2 stop) and intracranial internal carotid artery
- Technically inadequate CTA (poor contrast bolus, substantial motion, metal artifact that precludes accurate assessment of the intracranial arteries to the level of the distal M2 segments of the middle cerebral arteries)

3.3. Sample size

- Data will be collected from at least three centers in Europe, with a minimum of 60 samples per center.
- Initial target: 200
- Positive/negative ratio: 1/1

4. Possible investigational products

Preliminary selection of products that are potentially eligible for this study. We welcome feedback about additional products.

- Aidoc - Large Vessel Occlusion
- Arterys - Neuro AI
- Avicenna - CINA LVO
- Brainomix - e-CTA
- iSchemaView - Rapid CTA/LVO
- NICO.LAB - StrokeViewer
- Viz.ai - Viz LVO

5. Methods

5.1. Study parameters

5.1.1. Metrics

- Sensitivity
- Specificity
- F1-score

5.1.2. Subgroup analysis

Subanalysis is performed for e.g. LVO location and CT manufacturer. Vendors can notify us about subgroups that are outside the intended use of their product. Results regarding these products and subgroups will not be published.

5.1.3. Not-processed-rate

If there is no prediction for an image by the algorithm (rejected, error, or other reason), the empty field will be filled with 'LVO presence: No' to enable the metric calculation.

5.2. Data collection

5.2.1. Imaging data

- DICOM file of CT angiography (at least axial plane)
- DICOM file of NCCT (at least axial plane)
- Summary CT perfusion map (if available)

5.2.2. Clinical data



- Center: coded
- Patient age: years
- Gender: M/F
- Acquisition machine brand: coded
- Acquisition date: years
- LVO present: 0/1 (clinical diagnosis)
- Location of LVO:
 - M1/M2/ICA
 - Sidedness

5.3. Reference standard

5.3.1. The reference standard for the presence or absence of an intracranial vessel occlusion was set based on the evaluation by three experienced observers and the judgment of an independent neuroradiologist serving as referee in case of discrepancy between the observers. Anonymized clinical data, NCCT and CTP imaging, as well as the evaluation results of all observers were available to the referee.

5.3.2. These observers will verify the location of the large vessel occlusion:

- Sidedness: Left/Right/Main branch
- Vessel: M1/M2/ICA

5.4. Software prediction outcome

5.4.1. LVO presence (M1/M2/ICA): Yes/No

5.5. Reader study questions

5.5.1. Is a large vessel occlusion present?

- Yes/No

6. Statistical analysis

6.1. Comparing with average readers

- Sensitivity, specificity: confidence intervals with the Adjusted Wald Method, Bonferroni-corrected.