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A. Bani-Sadr, M. Aguilera, M. Cappucci, M. Hermier, R. Ameli, A. Filip, R. Riva, C. Tuttle, T.-H. Cho, L. Mechtouff, et al.

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## **Title Page**

### **Title of the manuscript:**

Comparison of magnetic resonance angiography techniques to brain digital subtraction arteriography in the setting of mechanical thrombectomy: a non-inferiority study.

### **Authors:**

Alexandre BANI-SADR<sup>1,2</sup>, MD; Marine Aguilera\*, MD<sup>1</sup>; MD-PhD; Matteo CAPPUCCI<sup>1</sup>, MD; Marc HERMIER<sup>1</sup>, MD-PhD; Roxana AMELI<sup>1</sup>, MD; Andrea Filip<sup>1</sup>, MD; Roberto RIVA<sup>1</sup>, MD; Celia Tuttle<sup>1</sup>, MD; Tae-Hee Cho<sup>3,4</sup>, MD-PhD; Laura MECHTOUFF<sup>3,4</sup>, MD-PhD; Norbert NIGHOGHOSSIAN<sup>3,4</sup>, MD-PhD; Omer EKER<sup>1,2</sup>, MD-PhD; Yves BERTHEZENE<sup>1,2</sup>, MD-PhD.

<sup>1</sup> Department of Neuroradiology, East Group Hospital, Hospices Civils de Lyon. 59 Bd Pinel, 69500, Bron, France.

<sup>2</sup> CREATIS Laboratory, CNRS UMR 5220, INSERM U1294, Claude Bernard Lyon I University. 7 avenue Jean Capelle O, 69100, Villeurbanne, France.

<sup>3</sup> Stroke Department, East Group Hospital, Hospices Civils de Lyon. 59 Bd Pinel, 69500, Bron, France.

<sup>4</sup> CarMeN Laboratory, INSERM U1060, Claude Bernard Lyon I University, 59 Bd Pinel, 69500, Bron, France

\*: Both authors contribute equally to this work.

Corresponding Author:

Dr Alexandre BANI-SADR

Department of Neuroradiology, East Group Hospital, Hospices Civils de Lyon. 59 Bd  
Pinel, 69500, Bron, France.

Mail : [apbanisadr@gmail.com](mailto:apbanisadr@gmail.com); [alexandre.bani-sadr@chu-lyon.fr](mailto:alexandre.bani-sadr@chu-lyon.fr)

Phone : +336 49 74 55 32

Fax : +334 72 35 73 29

**Title.**

Comparison of magnetic resonance angiography techniques to brain digital subtraction arteriography in the setting of mechanical thrombectomy: a non-inferiority study.

**Abstract****Introduction**

We performed a non-inferiority study comparing magnetic resonance angiography (MRA) techniques including contrast-enhanced (CE) and time-of-flight (TOF) with brain digital subtraction arteriography (DSA) in localizing occlusion sites in acute ischemic stroke (AIS) with a prespecified inferiority margin taking into account thrombus migration.

**Materials and Methods**

HIBISCUS-STROKE (CoHort of Patients to Identify Biological and Imaging markerS of

Cardiovascular Outcomes in Stroke) includes large-vessel-occlusion (LVO) AIS treated with mechanical thrombectomy (MT) following brain magnetic resonance imaging (MRI) including both CE-MRA and TOF-MRA. Locations of arterial occlusions were assessed independently for both MRA techniques and compared to brain DSA findings. Number of patients needed was 48 patients to exclude a difference of more than 20%. Discrepancy factors were assessed using univariate general linear models analysis.

**Results**

The study included 151 patients with a mean age of  $67.6 \pm 15.9$  years. In all included patients, TOF-MRA and CE-MRA detected arterial occlusions which were confirmed by brain DSA. For CE-MRA, 38 (25.17%) patients had discordant findings compared with brain DSA and 50 patients (33.11%) with TOF-MRA. The discordance factors were identical for both MRA techniques namely, tandem occlusions (OR=1.29,  $p=0.004$  for CE-MRA and OR=1.61,  $p<0.001$  for TOF-MRA), proximal internal carotid artery occlusions (OR=1.30,  $p=0.002$  for CE-MRA and OR=1.47,  $p<0.001$  for TOF-MRA) and time from MRI to MT (OR=1.01,  $p=0.01$  for CE-MRA and OR=1.01,  $p=0.02$  for TOF-MRA).

### Conclusion

Both MRA techniques are inferior to brain DSA in localizing arterial occlusions in LVO-AIS patients despite addressing the migratory nature of the thrombus.

### Keywords (meSH Terms):

- Stroke
- Thrombectomy
- Magnetic resonance angiography

## **Introduction**

Identification and precise localization of arterial occlusions are paramount in patients with acute ischemic stroke (AIS) who may require mechanical thrombectomy (MT) in case of large-vessel-occlusion (LVO) [1,2].

In clinical practice, most centers favor computed tomography (CT) scans with almost systematic cervical and intracranial vessel exploration. However, some centers prefer magnetic resonance imaging (MRI) for which the magnetic resonance angiography (MRA) protocol is variable. A recent multi-centric study comparing the effect on workflow and functional outcome of CT and MRI reported that only 28% of patients had had a contrast-enhanced MRA (CE-MRA) of the supra-aortic vessels and that all patients included underwent time-of-flight MRA (TOF-MRA) of the intracranial arteries [3]. Both MRA techniques have advantages and drawbacks. TOF-MRA is reported to have high sensitivity (85-100%) and specificity (91-100%) in identifying arterial occlusion and does not require the use of a contrast media [4,5]. However, TOF-MRA has a small field-of-view, longer acquisition duration and may overestimate the degree of stenosis [6,7]. Conversely, CE-MRA has shorter acquisition time, a larger field-of-view allowing complete evaluation of cervical arteries, and is less sensitive to blood flow artifacts [8].

Previous studies that compared the performance of CE-MRA and TOF-MRA in locating arterial occlusions in LVO-AIS patients considered brain digital subtraction

arteriography (DSA) as the reference [9,10]. However, recent studies have reported that thrombus regularly changes location between initial imaging and MT with an average reported rate of 20% [11–13]. This raises the question of the comparability of MRA techniques and brain DSA because the migratory nature of the thrombus was not addressed in previous studies (9,10).

In this setting, we aimed to perform a non-inferiority study comparing CE-MRA and TOF-MRA to brain DSA for locating arterial occlusions in LVO-AIS patients and to investigate factors of discrepancies between MRA techniques and brain DSA.

## **Material and Methods**

### Patient population

We performed a retrospective cohort study including patients from the HIBISCUS-STROKE cohort (CoHort of Patients to Identify Biological and Imaging markerS of CardiovascUlar Outcomes in Stroke; NCT: 03149705).

This cohort is an ongoing observational cohort conducted since October 2016 that includes patients referred to our stroke center for LVO-AIS of the anterior circulation and candidates for MT (9). Patients were included in this study if they underwent an initial MRI with TOF-MRA and CE-MRA followed by a brain DSA performed during MT. We excluded patients with posterior circulation AIS and those for whom one of the angiographic modalities was not available.

Baseline data on demographics characteristics were collected at hospital admission. In line with international guidelines, patients were additionally treated with intravenous thrombolysis immediately after brain MRI [14].

### Brain MRI

Brain MRI was performed on a 3T scanner (Philips Achieva, Philips Healthcare, Best, The Netherlands) and included parenchymal brain imaging sequences (axial DWI, T2 FLAIR, T2\*), angiographic sequences (3D TOF-MRA and CE-MRA). The total acquisition time was 15 minutes.

CE-MRA required the administration a bolus of gadoterate meglumine (Dotarem; Guerbet, Aulnay-sous-Bois, France) at a standard dose (0.1mmol/kg) via a peripheral venous catheter at 2ml/s. The arrival of the bolus in the arterial circulation required fast serial 2D images. The MRA acquisition parameters are presented in supplemental material 1.

#### DSA imaging

Brain DSA was performed immediately prior to MT by experienced neurointerventionalists using a biplanar system (Siemens Axiom Artis). Angiographic images acquired at two images per second with manual injection of iodinated contrast media. These images were further considered as the reference for extra- and intra-cranial artery analysis.

#### Image analysis

MRA images were reviewed, in random order, independently by two neuroradiologists blinded from clinical data, other MR sequences, and DSA. In case of discrepancy, a third neuroradiologist evaluated the images. Brain DSAs were also evaluated by two operators blinded from clinical data and MRIs, and a consensus was reached in case of discrepancy between them. All readings assessed the presence of an occlusion and its location according to the following classification: common carotid artery (CCA), internal carotid artery (ICA) including proximal ICA and distal ICA, proximal middle cerebral artery (MCA) including proximal M1 segment and distal M1 segment, and proximal M2 segment of MCA. In case of tandem occlusions,



both levels were reported. Image quality was assessed using a three-point subjective score: 0 = poor quality resulting in impossible interpretation; 1 = moderate quality with rare artifacts; 2 = good image quality with no artifacts.

### Statistical analysis

Data were summarized as mean ( $\pm$  standard-deviation), median (IQR) or counts (%) as appropriate. The accuracy, sensitivity, specificity, and predictive values of each MRA technique were calculated using brain DSA as reference and compared using McNemar's test. Inter-rater agreement for TOF-MRA, CE-MRA and brain DSA were assessed using the kappa coefficient [15].

This study was designated as a non-inferiority study to assess TOF-MRA and CE-MRA in locating arterial occlusion in AIS patients compared to brain DSA. The prespecified non-inferiority margin for discrepancy rate was chosen at 20% because this is the average reported rate of thrombus migration [11–13]. Assuming 100% accuracy for brain DSA, 48 patients were needed to be 90% sure that a 95% one-sided confidence interval would exclude a difference of  $>20\%$ . Univariate analyses using general linear models were performed to assess potential factors of discrepancies namely time between MRI and MT, tandem occlusion, intravenous thrombolysis and image quality. A two-sided p-value  $< 0.05$  was considered as statistically significant. All statistical analyses were performed with the R software, version 3.2.1 (R foundation for Statistical Computing, Vienna, Austria).

## **Results**

### Demographics and image characteristics of included patients

During the study period, 151 patients (on a base of 174 patients) met the inclusion criteria. Twenty-three patients were excluded because of incomplete MRI

protocol (n=5) or poor image quality either for TOF-MRA (n=2), CE-MRA (n=2) or brain DSA (n=5). Nine patients with posterior site occlusion were also excluded.

The population included 85 males (56.29%) and 66 females (43.71%) with a mean age of  $67.6 \pm 15.9$  years (range: 27-94). All patients underwent MT and 79 (52.31%) of them received intravenous thrombolysis. The mean delay between brain MRI and DSA was  $67.22 \pm 58.53$  min. The distribution of arterial occlusion sites documented by brain DSA and both MRA techniques is presented in supplemental material 2 and image quality is reported in supplemental material 3.

#### Comparison of CE-MRA and brain DSA

In all included patients, CE-MRA detected at least one arterial occlusion. The location of occlusion site was discordant with brain DSA findings in 38 (25.17%) patients. Inter-rater agreement was almost perfect CE-MRA ( $\kappa=0.92$ , 95% CI [0.86-0.97],  $p<0.01$ ). As presented in Table 1, CE-MRA exhibited excellent diagnostic performance except for moderate specificity for the distal ICA and the proximal M1 segment of the MCA. Figure 1 presents an example of a pseudo-occlusion of the proximal ICA which illustrates the limitation of CE-MRA in assessing proximal ICA patency.

In univariate analysis, discrepancies between CE-MRA and brain DSA were associated with tandem occlusion (OR=1.29,  $p=0.004$ ), proximal ICA occlusion (OR=1.30,  $p=0.002$ ) and time from MRI to MT (OR=1.01,  $p=0.01$ ) but not with intravenous thrombolysis ( $p=0.96$ ), nor with image quality ( $p=0.69$ ).

#### Comparison of TOF-MRA and brain DSA

TOF-MRA identified at least one arterial occlusion for each included patient. Occlusion site was discordant in 50 subjects (33.11%) compared with brain DSA. Inter-rater agreement was also almost perfect ( $\kappa=0.98$ , 95% CI [0.95-1.00],  $p<0.001$ ). As presented in Table 2, TOF-MRA had low sensitivity for tandem occlusions. Figure 2 presents an example of tandem occlusions misdiagnosed with TOF-MRA.

Discrepancies between TOF-MRA and brain DSA were associated with tandem occlusion (OR=1.61,  $p<0.001$ ), proximal ICA occlusion (OR=1.47,  $p<0.001$ ) and time from MRI to MT (OR=1.01,  $p=0.02$ ) but not with intravenous thrombolysis ( $p=0.97$ ), nor with image quality ( $p=0.68$ ). Supplemental material 3 presents an example of thrombus migration.

#### Comparison of CE-MRA and TOF-MRA

Compared to TOF-MRA, CE-MRA was statistically more accurate for proximal M1 occlusion ( $p=0.002$ ) and tandem occlusions ( $p<0.001$ ). An example of a tandem carotid-sylvian occlusion is shown in Figure 2.

For all other locations, there was no statistically significant difference between the two MRA techniques (all  $p>0.68$ ).

#### **Discussion**

The aim of this retrospective cohort study was to determine whether CE-MRA and TOF-MRA were non-inferior compared to brain DSA in localizing the arterial occlusion site in patients with LVO-AIS when addressing the migratory nature of the thrombus.

Our results demonstrated that both MRA are inferior to brain DSA and this might be explained by three main reasons.

First, thrombus location regularly changes between initial imaging and DSA with an average reported rate of 20% [11–13]. Occlusion site discrepancies between MRA techniques and brain DSA were associated with time from baseline MRI to brain DSA but not with intravenous thrombolysis. These findings are in disagreement with previous articles as several authors reported that thrombus migration was associated with intravenous thrombolysis [11–13]. A possible explanation is a different definition of thrombus migration, with most authors defining it as any downstream migration of the clot. In our study, we only considered a different location according to the pre-established grid as a discrepancy. As a result, we may have misrecognized millimeter-scale migrations.

Second, both MRA techniques have impaired accuracies in case of tandem occlusions, i.e. 20.53% in our study population. As a blood-flow based technique, TOF-MRA does not allow precise assessment of intracranial vasculature in cases of occlusion and/or severe stenosis of the carotid bulb. Likewise, contrast flow can also be impeded by an extracranial ICA stenosis and/or obstruction of the proximal ICA that may also preclude precise assessment of intra-cranial vasculature with CE-MRA [8,16]. Third, an intra-cranial clot may lead to extracranial ICA pseudo-occlusions in about 11-46% of cases [17–19]. The underlying mechanism of pseudo-occlusion is a stagnant contrast flow proximal to an intracranial occlusion and has also been reported for CT angiography [20–22].

As a result, CE-MRA had excellent sensitivity but moderate specificity for tandem occlusions. In our study, the false positive rate of CE-MRA (20.69%) was lower than the reported rate for CT angiography (30.4%) by M. Roche et al. [21]. A possible explanation is that CE-MRA acquisition is later than that of CT angiography because of a longer acquisition time. In addition, we found that CE-MRA was more accurate

for tandem occlusions and the M1 proximal segment of the MCA which is in agreement with previous studies (9,10). The most likely explanation is that the CE-MRA field-of-view extends from the aortic arch to the distal intra-cranial arteries in contrast to TOF-MRA that only assesses intra-cranial vasculature. Since TOF-MRA is inferior to CE-MRA and time-consuming, our results suggest that TOF-MRA in the MRA protocol is superfluous for AIS suspicion.

Knowledge of the limitations of the MRA techniques is essential. Most importantly, misdiagnosis of tandem occlusions can lead to severe issues. It may directly impact the management of AIS patients since recent studies suggest that carotid stent placement with anti-platelet therapy may be the most effective therapy for tandem occlusions [23,24]. In addition, this might influence the indications for intravenous thrombolysis as its efficacy is reported to be weak for tandem occlusions [25].

This study has several limitations. First, this was a single-center retrospective cohort study. In addition, we only studied early CE-MRA. Recently, some authors compared early and delayed CE-MRA for the assessment proximal ICA patency [26]. They concluded that delayed CE-MRA may improve accuracy and reliability [26]. In addition, none of the included patients had severe arterial stenosis, which probably explains the absence of false positives for TOF-MRA. In clinical practice, it is difficult to distinguish severe intracranial stenosis from arterial occlusion with TOF-MRA, unlike CE-MRA [6,7].

In conclusion, both CE-MRA and TOF-MRA are inferior to brain DSA in locating arterial occlusion in LVO-AIS patients despite addressing the migratory nature of the thrombus because both techniques have impaired accuracies for tandem occlusions and for assessing proximal ICA patency.

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**Declarations of interest:**

None

**Tables**

Table 1. Diagnostic performances of CE-MRA

	Accuracy % [95% CI]	Sensitivity %	Specificity %	PPV %	NPV %
Tandem	90.73 [84.93-94.84]	95.00	74.19	93.44	79.31
Proximal ICA	94.04 [88.99-97.24]	93.22	96.97	99.10	80.00
Distal ICA	92.72 [87.34-96.31]	98.45	59.09	93.38	86.67
Proximal M1	86.09 [79.53-91.18]	87.36	84.38	83.08	83.08
Distal M1	86.75 [80.29-91.72]	90.68	72.73	92.24	68.57
Proximal M2	92.72 [87.34-96.31]	97.52	73.33	93.65	88.00

Abbreviations: CE-MRA= Contrast-Enhanced Magnetic Resonance Angiography; PPV= Positive Predictive Value; NPV= Negative Predictive Value; ICA= Internal Carotid Artery; M1: First segment of the Middle Cerebral Artery; M2: Second segment of the Middle Cerebral Artery; 95% CI = 95% Confidence Interval.

Table 2. Diagnostic performances of TOF-MRA

	Accuracy % [95% CI]	Sensitivity %	Specificity %	PPV %	NPV %
Tandem	78.81 [71.42-85.03]	3.23	98.33	33.33	79.73
Proximal ICA	94.04 [88.99-97.24]	94.07	93.94	98.23	81.58
Distal ICA	92.05 [86.53-95.83]	98.45	54.55	92.70	85.71
Proximal M1	76.82 [69.27-83.29]	89.66	59.38	75.00	80.85
Distal M1	84.77 [78.03-90.09]	90.68	63.64	89.92	65.62
Proximal M2	91.39 [85.73-95.34]	97.52	66.67	92.19	86.96

Abbreviations: TOF-MRA= Time-Of-Flight Magnetic Resonance Angiography; PPV= Positive Predictive Value; NPV= Negative Predictive Value; ICA= Internal Carotid Artery; M1: First segment of the Middle Cerebral Artery; M2: Second segment of the Middle Cerebral Artery; 95% CI = 95% Confidence Interval.

## **Figure Legends**

### Figure 1. An example of pseudo-occlusion of proximal ICA

In this patient, TOF-MRA (Fig1.A) revealed a signal void (*white arrow*) in the right proximal ICA suggesting an occlusion of the latter. CE-MRA (Fig. 1B) shows opacification defects of the proximal ICA and the proximal M1 segment of the MCA (*white arrows*) that suggest a tandem occlusion.

Brain DSA findings (Fig. 1C) are discordant by showing an occlusion of the right carotid termination (*black arrow*) responsible for severe slowing of blood flow and explaining the abnormalities of proximal ICA found both for TOF-MRA and CE-MRA.

Abbreviations: TOF-MRA= Time-Of-Flight Magnetic Resonance Imaging; ICA= Internal Carotid Artery; MCA= Middle Cerebral Artery; CE-MRA= Contrast-Enhanced Magnetic Resonance Imaging; DSA= Digital Subtraction Angiography



Figure 2. An example of tandem occlusion

In this example, TOF-MRA (Fig. 2A) revealed a signal void in the right proximal ICA (*white arrow*) and, CE-MRA (Fig. 2B) demonstrated a tandem occlusion including the proximal ICA and the proximal M1 segment of the MCA (*white arrows*). Brain DSA (Fig 2.C and 2.D) confirms tandem occlusion by visualizing opacification defects at the origin of the right proximal ICA and the proximal M1 segment of the MCA (*black arrows*).

Abbreviations: TOF-MRA= Time-Of-Flight Magnetic Resonance Imaging; CE-MRA= Contrast-Enhanced Magnetic Resonance Imaging; MCA= Middle Cerebral Artery;

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