

SUPPLEMENTAL MATERIAL ON:

The added value of a blinded outcome adjudication committee in an open-label randomized stroke trial

Nadinda A.M. van der Ende, MD;^{1,2} Bob Roozenbeek, MD, PhD;^{1,2} Olvert A. Berkhemer, MD, PhD;¹⁻⁴ Peter J. Koudstaal, MD, PhD;¹ Jelis Boiten, MD, PhD;⁵ Ewoud J. van Dijk, MD, PhD;⁶ Yvo B.W.E.M. Roos, MD, PhD;⁴ Robert J. van Oostenbrugge, MD, PhD;⁷ Charles B.L.M. Majoie, MD, PhD;³ Wim van Zwam, MD, PhD;⁸ Hester F. Lingsma, PhD;⁹ Aad van der Lugt, MD, PhD;² Diederik W.J. Dippel, MD, PhD;¹ on behalf of the MR CLEAN Investigators¹⁰

Departments of Neurology¹, Radiology and Nuclear Medicine², Public Health⁹, Erasmus MC University Medical Center, Rotterdam, the Netherlands;

Departments of Radiology and Nuclear Medicine³, and Neurology⁴, Amsterdam UMC, University of Amsterdam, Amsterdam, the Netherlands;

Department of Neurology⁵, Haaglanden Medical Center, The Hague, The Netherlands;

Department of Neurology⁶, Radboud University Medical Center, Nijmegen, The Netherlands;

Departments of Neurology⁷, and Radiology and Nuclear Medicine⁸, Cardiovascular Research Institute Maastricht, Maastricht University Medical Center, Maastricht, the Netherlands;

The MR CLEAN Investigators¹⁰ are listed in the Appendix.

Supplemental Table I. Guidelines for Reporting Reliability and Agreement Studies (GRRAS).

Section	Item number	Description	Addressed on page number
Title and Abstract	1	Identify in title or abstract that interrater/intrarater reliability or agreement was investigated.	3
Introduction	2	Name and describe the diagnostic or measurement device of interest explicitly.	5-6
	3	Specify the subject population of interest.	5-6
	4	Specify the rater population of interest (if applicable).	5-6
	5	Describe what is already known about reliability and agreement and provide a rationale for the study (if applicable).	5-6
Methods	6	Explain how the sample size was chosen. State the determined number of raters, subjects/objects, and replicate observations.	6-7
	7	Describe the sampling method.	6-7
	8	Describe the measurement/rating process (e.g. time interval between repeated measurements, availability of clinical information, blinding).	6-7
	9	State whether measurements/ratings were conducted independently.	7
	10	Describe the statistical analysis.	8

Results	11	State the actual number of raters and subjects/objects which were included and the number of replicate observations which were conducted.	8-9 + Figure 1
	12	Describe the sample characteristics of raters and subjects (e.g. training, experience).	8 + Table 1
	13	Report estimates of reliability and agreement including measures of statistical uncertainty.	9 + Table 2-3
Discussion	14	Discuss the practical relevance of results.	10-13
Auxiliary material	15	Provide detailed results if possible (e.g. online)	NA

NA indicates not applicable.

Supplemental Table II. Three month follow-up Case Report Form

Date of three month follow-up: ___ - ___ - ___ (dd-mm-yyyy) Who completed assessment: _____

Patient deceased: Yes No

Date of death: _____

Days in a nursing home after discharge: _____ days Length: _____

Days in a rehabilitation center after discharge: _____ days

Days in a geriatric rehabilitation unit after discharge: _____ days Smoking on admission? _____

Have you been re-admitted to a hospital after discharge? _____ days

Current residence:

Home Nursing home Other: _____

Rehabilitation center Hospital

Geriatric rehabilitation unit Friends/family

Days in a day care facility after discharge _____ days

Hours of speech and language therapy after discharge: _____ hours

Hours of physiotherapy after discharge: _____ hours

Hours of ergo therapy after discharge? _____ hours

Do you feel that you have made a complete recovery from your stroke? Yes No

Does the person have difficulty reading or writing? Yes No

Does the person have difficulty speaking or finding the right word? Yes No

Does the person have problems with balance or coordination? Yes No

Does the person have visual problems? Yes No

Does the person have numbness (face, arms, legs, hands, feet)? Yes No

Has the person experienced loss of movement (face, arms, legs, hands, feet)? Yes No

Does the person have difficulty with swallowing? Yes No

Any other problems or difficulties? Yes No

Is assistance needed for activities of daily living? Yes No

Is assistance essential for preparing a simple meal?
(For example, able to prepare breakfast or a snack) Yes No

Is assistance essential for basic household chores?
(For example, finding and putting away clothes, clearing up after a meal. Excludes chores that do not need to be done every day, such as using a vacuum cleaner.) Yes No

Is assistance essential for managing finances? Ja Nee

Is assistance essential for local transportation?
(Patients may drive or use public transport to get around. Ability to use a taxi is sufficient, provided the person can phone for it themselves and instruct the driver.) Yes No

Is assistance essential for local shopping?
(Local shopping: at least able to buy a single item.) Yes No

Before stroke was the person looking after family at home? Yes No

If yes: Since stroke has there been a change in their ability to look after family at home? Yes No

Before stroke, was the person working or seeking work (or studying as a student)? Yes No
(If the person was not employed or seeking work before stroke, or the person was retired then indicate 'No')

If yes: Since stroke has there been a change in the person's ability to work or study?
(Change in ability to work or study includes loss of employment or reduction in level of responsibility; change in education or problems with study). Yes No

Before stroke did the person have regular free-time activities? Yes No

If yes: Since stroke has there been a change in their ability to participate in these activities? Yes No

Do you live alone? Yes No

Is there someone who visits you regularly and also helps you with something? Yes No

Do you have professional help? *(housekeeping or home care)* Yes No

Are there other illnesses or shortcomings that make you less able to take care of yourself or make you less mobile? Yes No

Can you easily be home alone for a day? Yes No

Can you easily be home alone for a week? Yes No

BARTHEL INDEX

Feeding

- Unable
- Needs help cutting, spreading butter, or requires modified diet
- Independent

Transfer (bed to chair and back)

- Unable, no sitting balance
- Major help (one or two people, physical), can sit
- Minor help (verbal or physical)
- Independent

Grooming

- Needs help with personal care
- Independent face/hair/teeth/shaving (implements provided)

Toilet use

- Dependent
- Needs some help, but can do something alone
- Independent (on and off, dressing, wiping)

Bathing

- Dependent
- Independent (or in shower)

Mobility (on level surfaces)

- Immobile or < 50 yards
- Wheelchair independent, including corners, > 50 yards
- Walks with help of one person (verbal or physical) > 50 yards
- Independent (but may use aid, e.g., cane) > 50 yards

Stairs

- Unable
- Needs help (verbal, physical, carrying aid)
- Independent

Dressing

- Dependent
- Needs help but can do about half unaided
- Independent (including buttons, zips, laces, etc)

Bowels

- Incontinent (or needs to be given enemas)
- Occasional accident
- Continent

Bladder

- Incontinent, or catheterised and unable to manage alone
- Occasional accident
- Independent

EQ5D

Mobility

- I have no problems in walking
- I have some problems in walking
- I am confined to bed

Self-Care

- I have no problems with self-care
- I have some problems with washing or dressing myself
- I am unable to wash or dress myself

Usual activities (e.g. work, study, housework, family or leisure activities)

- I have no problems with performing my usual activities
- I have some problems with performing my usual activities
- I am unable to perform my usual activities

Pain / Discomfort

- I have no pain or discomfort
- I have some moderate pain or discomfort
- I have extreme pain or discomfort

Anxiety / Depression

- I am not anxious or depressed
- I am moderately anxious or depressed
- I am extremely anxious or depressed

Assessment by:

- Patient
- Proxy

