

Results from software based formal training of **BI924** MR image reading in the WAKE-UP trial

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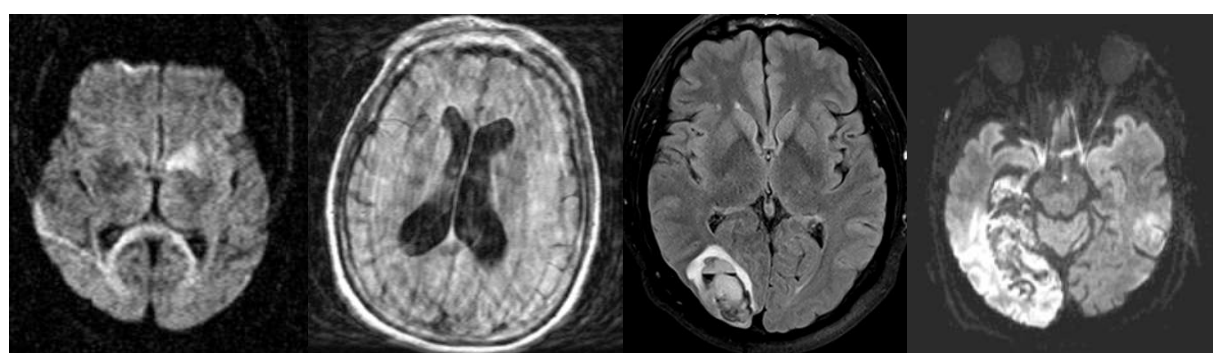
Background: WAKE-UP is an investigator initiated, European, multicentre, randomized, double-blind, placebo-controlled clinical trial of MRI-based thrombolysis with Alteplase in stroke patients with unknown time of symptom onset e.g. wake-up stroke. Patients are randomized if MRI shows a mismatch between a visible acute ischemic lesion on DWI but no parenchymal hyperintensity on FLAIR (DWI-FLAIR-mismatch) indicating an ischemic lesion within the time-window for thrombolysis (=4.5 h after onset).

We report on the formal software-based training to qualify readers to make correct inclusion decisions.

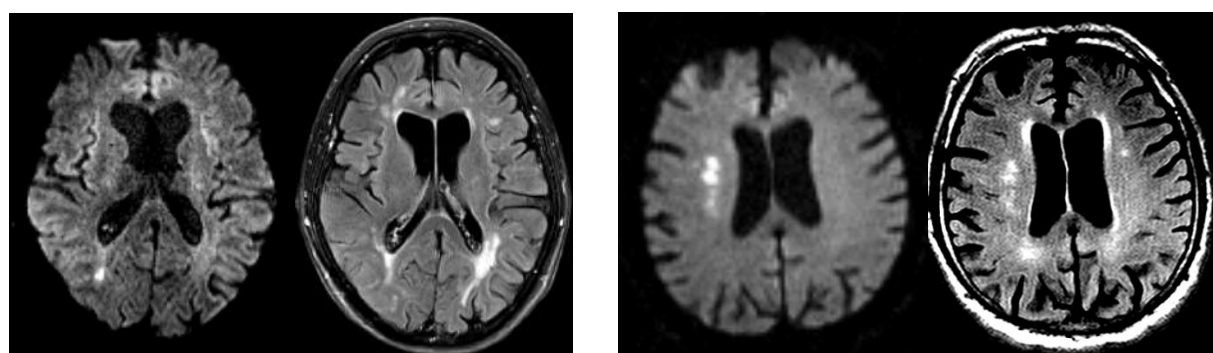
Methods: 65 cases were selected featuring patients with key imaging inclusion and exclusion findings (e.g. DWI-FLAIR mismatch, severe leukoaraiosis, poor image quality, intracerebral hemorrhage). A detailed handbook and a short guideline introducing inclusion and exclusion criteria were prepared.

A software package was developed based on MeVisLab to present selected cases and ask for answers in a standardized electronic case report form on image quality, presence of hemorrhage, DWI and FLAIR lesions and a final inclusion decision. Readers could work through a number of random training cases where feedback from comparing their answers to a reference reader was given.

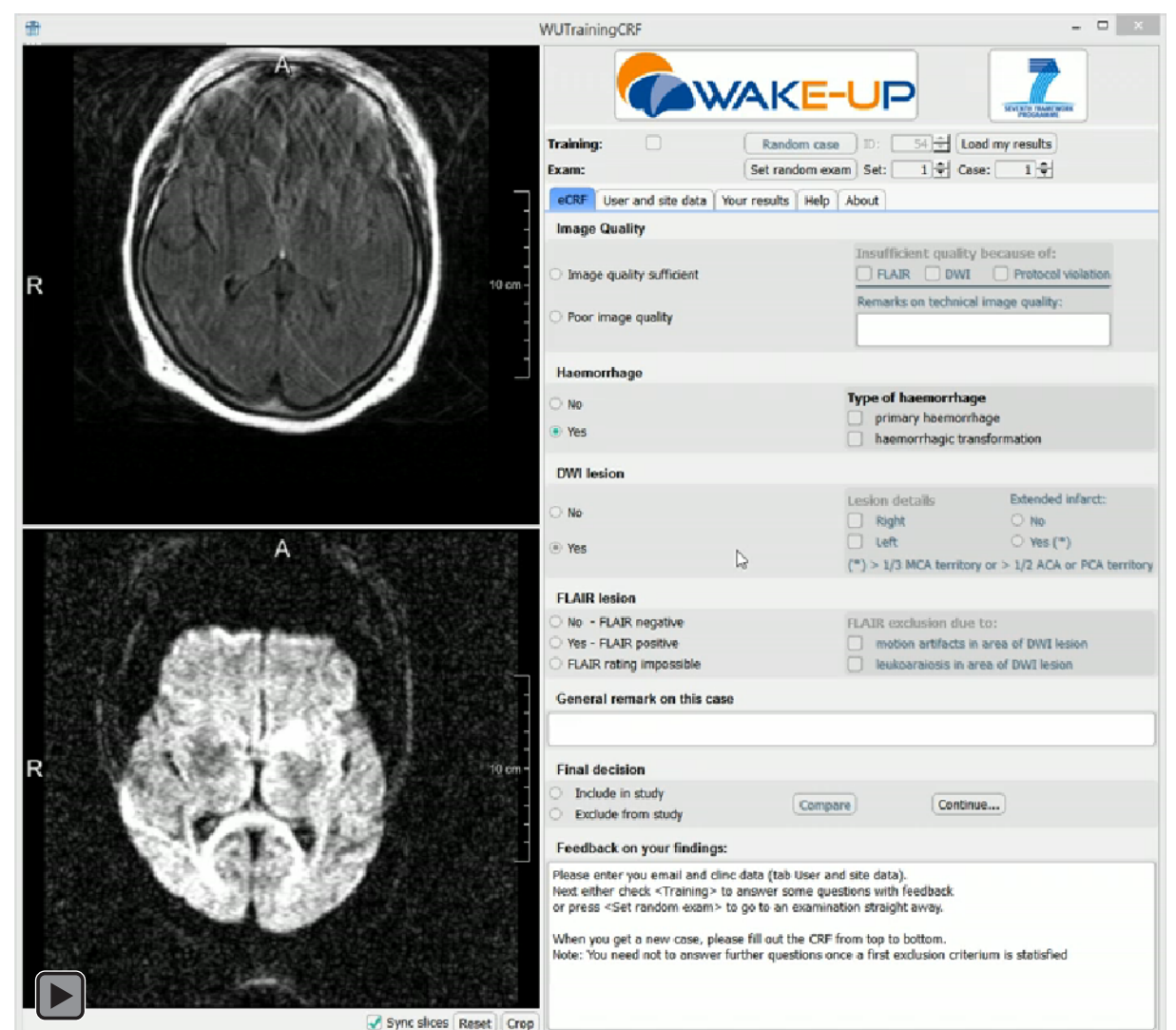
Examples of cases to be excluded:



Poor DWI / FLAIR quality (movement?) / bleeding / extended infarct



Leukoaraiosis near lesion / FLAIR positive lesion



Electronic case report form used for reader training and examination. Items on 4 categories (Image quality, presence of hemorrhage, DWI resp. FLAIR lesion features and final include decision are recorded.

After a training round one of 5 possible sets of 13 exam tasks was randomly assigned. Answers were centrally reviewed and formal approval as a reader in WAKE-UP was granted, if at most 2 inclusion decisions differed from the reference.

Results: On intermediate evaluation 165 readers from 29 sites in 6 countries passed the exam (Jun 2012 - Nov 2013). Thereof 38.9% passed without error, 39.5% with one and 21.1% with two errors. 12 readers failed in a first exam, 50% thereof had 9 resp. 10 correct out of 13 decisions. Readers spent 13.4 minutes (median), typical exam durations were in the Q10-Q90 range from 10 to 22 min.

Frequent reasons for differences with the reference reader's decision were overlooked second stroke lesions, borderline image quality and cases with leukoaraiosis interfering with the judgment of the acute stroke lesion.

Conclusion: Formal reader training using software for training and examination is feasible, time effective and a valuable means of quality assurance in a large multicenter trial involving imaging inclusion and exclusion criteria.

Further information on the WAKE-UP trial itself is available at:
<http://www.wakeup-stroke.eu/>



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