Assessment of Direct Oral Anticoagulant Status Using the DOASENSE Dipstick in Thrombolysis Eligible Patients With Stroke: Proof-of-Concept Study

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This is the first publication in a major peer-reviewed journal on a study using the *DOAC Dipstick* test in a stroke center setting, where every minute counts in therapeutic decision making, e.g. proceeding with thrombolysis. Thrombolysis in acute stroke may be safe depending on the direct oral anticoagulant (DOAC) plasma concentration level, but timely access to DOAC lab assays is limited. Thresholds of plasma concentrations are still controversial for conduction of intravenous thrombolysis in patients with ischemic stroke, or for administration of DOAC antidotes.

The authors performed a single-center, prospective, 2-armed observational study at a high-volume primary stroke center in Australia.
The acute arm recruited patients eligible for thrombolytic therapy (n=17; Rivaroxaban, Apixaban, Dabigatran). Expedited plasma DOAC level determination and *DOAC Dipstick* tests were performed during the acute stroke assessment. The subacute arm recruited ischemic stroke inpatients, following DOAC initiation for secondary prevention (n=24) by assessing plasma DOAC level at 4 to 6 hours following ingestion to determine the agreement of results. DOAC levels (threshold >30 ng/mL) were determined by chromogenic substrate tests and *DOAC Dipstick* test following the instructions for use.

Results

- Median time to result for plasma DOAC level versus *DOAC Dipstick* test:
  52 min (interquartile range, 38–67) for lab assay; versus
  20 min (interquartile range, 17–24) for *DOAC Dipstick*, including urine acquisition time.
- 95% (16/17) and 92% (22/24) agreement between the *DOAC Dipstick* results and DOAC plasma level >30 ng/mL for all DOACs in the acute and subacute treatment arm.
- No false negatives in the acute arm.
- Two false negative results with corresponding plasma levels of 56 and 58 ng/mL in the subacute arm: an apixaban case in which diluted urine was collected from an indwelling catheter bag and a dabigatran case in an elderly lady with urinary incontinence.
- 10 patients not on DOAC tested negative on *DOAC Dipstick* and plasma concentration.

The authors conclude that their study provides preliminary evidence for using the *DOAC Dipstick* test to identify patients for prompt thrombolysis, who would have been excluded otherwise (based on their clinical history alone).

Conclusion:
This is the first study on the use of the *DOAC Dipstick* test in a stroke center.

- **Rapid determination of DOAC status may improve targeting of reversal agent administration, minimizing thrombolysis delay.**
- **Data provide preliminary evidence for using the *DOAC Dipstick* test strips to identify patients for prompt thrombolysis.**

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