A Bedside Urine Strip Test On Identifying Anticoagulation With Direct Oral Anticoagulants at a High-Volume Emergency Department – A Diagnostic Test Accuracy Study

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Background

Rapid and reliable detection of effective anticoagulation with a direct oral anticoagulant (DOAC) is critical in medical emergency situations. An accurate bedside test could support fast decision-making, help avoiding potentially fatal bleeding complications and may improve patient care and safety. A recently developed point-of-care strip test DOAC Dipstick is intended for detection of the presence of direct oral thrombin (DTI) and factor Xa inhibitors (rivaroxaban, edoxaban, apixaban) (DXI) in urine by visual color identification of pads specific for detecting DTI and DXI providing qualitative test results after 10 minutes.

Objective

The aim of the study is to determine the diagnostic test accuracy (DTA) of the qualitative results of the DOAC Dipstick (index test; figure 1) in patients routinely treated at a high-volume emergency department in relation to cut-off values in plasma and urine samples (figure 2) using liquid chromatography with mass spectrometry (LC-MS/MS) and other coagulation tests.

Methods

The prospective cohort study enrolls consecutive adult patients with known or presumed DOAC intake at the emergency department at the Vienna General Hospital. The study was approved by the local Ethics Committee in accordance with Helsinki declaration. Patient recruitment started January 2019 and ended August 2020. Patients were recruited 24/7, according to the need for a constantly available test at an emergency department. The DOAC Dipstick test was evaluated using a pocket-guide (figure). Patients' plasma was collected (3.8% sodium citrate/blood, 1/10, centrifuged for 10 min at room temperature within 2 hrs, performance of clotting assays, followed by freezing and storage at -80°C for LC-MS/MS and other coagulation tests) as well as urine samples for immediate analysis with DOAC Dipstick, visual documentation of pads of DOAC Dipstick, digital photographic documentation and freezing of an aliquot at -80°C for LC-MS/MS. For statistical analysis DTA standard measures will be calculated using dichotomous data of the DOAC Dipstick and of results of LC-MS/MS and coagulation tests.

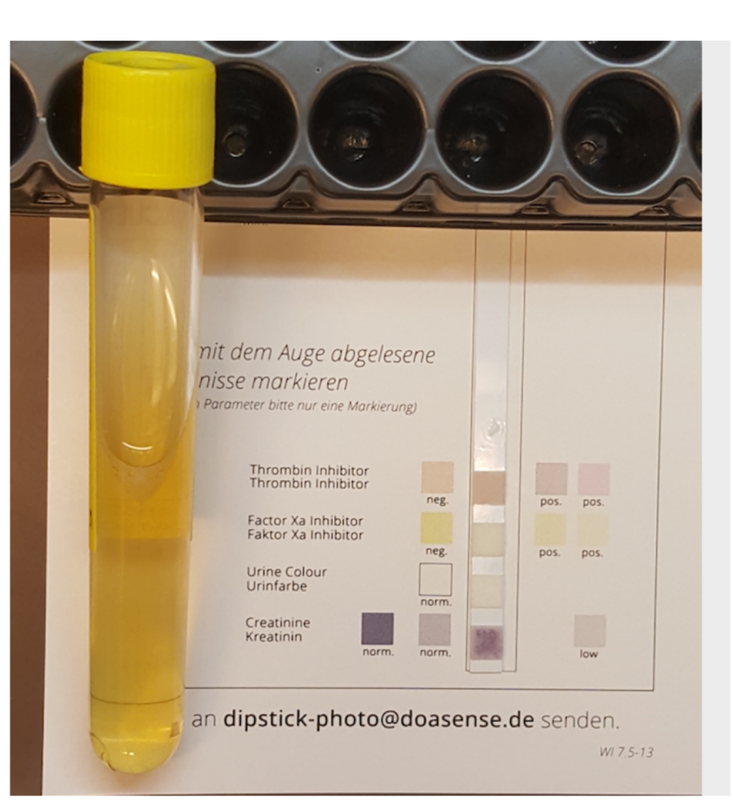

Figure 2: Urine sample and DOAC-Dipstick

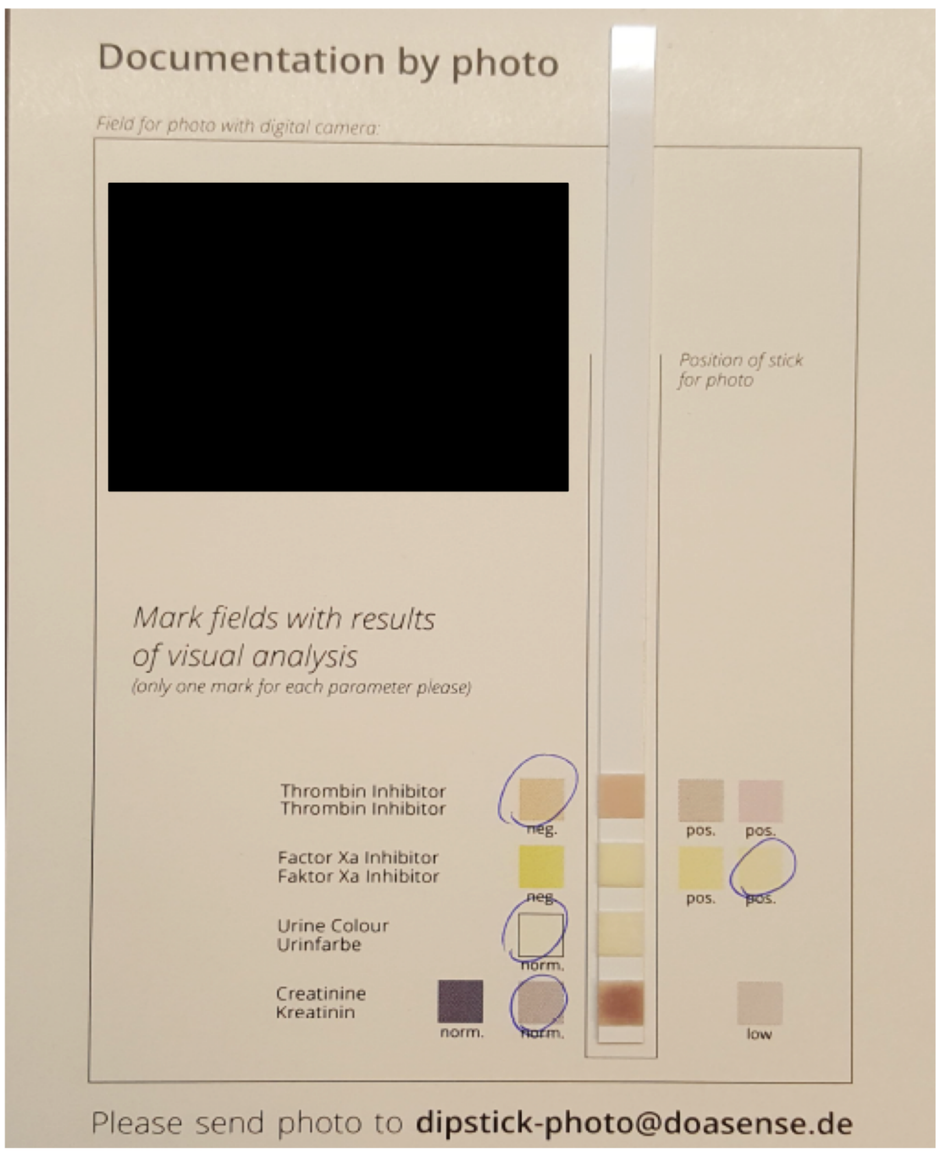

Figure 1: Results of DOAC-Dipstick

Results & Conclusion

Recruitment was completed (n=320) and results are under evaluation. To our knowledge this is the first study evaluating the accuracy of DOAC Dipstick versus plasma and urine concentrations in patients treated with DOACs and hospitalized for acute diseases to a high-volume emergency department.

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