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POSTER ABSTRACTS

331.THROMBOSIS

Analysis of Inter-Observer Agreement of Adjudication of Colors of Pad Colors of Doac Dipstick to Determine Presence or Absence of Direct Oral Anticoagulants in Outpatients' Urine Samples

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Abstract Background: The efficacy and safety of direct oral anticoagulants (DOACs) in patients with thromboembolic disease is closely related to patient's adherence to therapy. Objective documentation of drug intake is a useful tool for patients' education and improvement of adherence to treatment but may be improved by accurate point-of-care (POCT) testing. Results of DOAC Dipstick may be one of these methods but may depend on interpretation variability.
Aim: We aim to analyze the inter-observer agreement of DOAC Dipstick near-patient device in outpatients on stable anticoagulation with rivaroxaban (R), apixaban (A) and dabigatran (D).
Methods: A prospective observational cohort study was performed including patients on active treatment with R, A, and D for secondary VTE prevention. All participants were routinely assessed for DOACs' plasma concentration using STA ® Liquid anti-Xa and STA ® Liquid anti-IIa chromogenic assays , and creatinine clearance (Cockroft -Gault equation). DOAC Dipstick test was performed in patients' urine samples were performed by trained staff according the instructions for use. The assessment was based on pads'colors which are specific for indicating the presence and absence of factor -Xa (FXA) and thrombin inhibitors (THI). In order to assess inter-observer agreement, the study nurse performing the test and the medication-prescribing physician were in charge of evaluating independently each test strip. THI pad and FXA pad served as negative control for patients treated with R and A, and D, respectively. Inter-observer agreement was calculated by Cohen's kappa coefficient (kappa index).
Results: A new interim analysis shortly before study termination was performed after enrolment of 79 patients (female/ male 44/35, age 56 ± 18 years, mean and standard deviation). Of those, 20% (n=17) were treated for deep vein thrombosis, 13% (n=10) for pulmonary embolism (PE), 40% (n=32) for recurrent thromboembolic disease, 18.3% (n=13), for cancer-associated thrombosis, 6 for antiphospholipid syndrome (n= 5), 2 % (n=2) for AF. 60 % (n=48) were treated with R, 37% (n=29) with A and 3% (n=2) with D. All patients had normal renal function. Anti-factor Xa levels were determined with a median value of 156.6±129.2 ng/ml and anti-factor IIa levels with 191.66±110.34 ng/mL. The inter- observer agreement of colors of FXA and THI pads of urine samples was 0.99 for positivity for R, A, and D. Pads that served as negative controls were assessed correctly as negative by both observers in all cases (kappa index 1.0).
Conclusion: Given the encouraging results, the ongoing study should allow the device's validation as an accurate, easy-to-use assessment tool for determination of the presence or absence of DOACs in patients' urine samples also based on a very low inter-observer variability. The aforementioned data confirm the results of the first interim analysis presented in the ISTH 2021 congress.

Disclosures Harenberg: *DOACSENCE:* Other: Founder and managing director.

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