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Results of DOAC Dipstick test in outpatients with venous thromboembolic disease are comparable to plasma levels of direct oral inhibitors -an efficient assessment tool.

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INTRODUCTION

The in vitro medical device DOAC Dipstick (DOASENSE GmbH) was developed based on the rationale that DOACs are excreted into the urine, thus may be detectable .It gives qualitative results regarding the absence or presence of DOACs in a patient's urine sample for both direct oral factor Xa inhibitor and oral thrombin inhibitors. This single-use assay has a turnaround time of 10 minutes, and results can be determined by visual identification of specific colors with the naked eye

AIM

Primary objective: to validate the use of the DOAC Dipstick device in the evaluation of the presence of DOACs in the urine of out-patients receiving these drugs for secondary prevention of VTE

Secondary objective: To test the sensitivity and sensibility of the DOAC Dipstick device to DOACs in the urine of patients and to compare it the concentration of these DOAC in patients' plasma measured with the respective specific chromogenic assays.

METHOD

This is an ongoing observational cohort study. We present the results of the consecutively enrolled patients with documented VTE followed at the outpatient care unit of the Antithrombotic Clinic of the APHP.6 (Tenon and Saint Antoine University hospitals) as of the 1st of December 2019 to date. The subjects were on active antithrombotic treatment with rivaroxaban or apixaban for secondary prevention of VTE and fulfill the required inclusion and exclusion criteria for eligibility for participation.

The DOAC Dipstick test strips were incubated shortly in patients' urine samples. Then, after 10 min the colors of the factor Xa and thrombin inhibitor pads were adjudicated by comparison with a color scale on the test tube's label by the treating physician according to the description in the instructions for use. All participants were routinely assessed for anti-factor Xa activity in plasma using the specific chromogenic assays. Renal function was assessed by determination of serum creatinine according to the Cockroft –Gault equation.

RESULTS

Interim analysis was performed after enrolment of 72 patients (female/ male 40/32 age 56 ± 16 years, mean and standard deviation). Of these, 15.4% (n=11) were treated for deep vein thrombosis (DVT), 11.2% (n=8) for pulmonary embolism (PE), 47.8% (n=34) for recurrent thromboembolic disease, 18.3% (n=13), for cancer-associated thrombosis ,6.9% for APS (n= 5), 1.3% (n=1) for AF , of which 66.1 % (n=47) were treated with rivaroxaban , 32.3% (n=23) with apixaban and 2.8% (n=2) with dabigatran . All patients had normal renal function. The anti-Xa levels were of a median value of 151.41 ±114.79 ng/ml and the anti-IIa levels of 191.66±110.34 ng/mL . The factor Xa inhibitor pad of urine samples was as true positive in 70/71 cases (98.5%) and false negative in 1/71 cases (1.4%) . Negative control pad was negative in all cases. All of the above are summarized on table 1.

Thrombotic localisation	Patient number		DOAC			plasma anti-Xa levels	151.4 ± 114.79
DVT	11 (15.4%)		Rivaroxaban	47 (66.1%)		plasma anti-IIa levels	191.66±110.34
PE	8 (11.2%)		Apixaban	23 (32.3)			
Recurrent thrombosis	34 (47.8%)		Dabigatran	2 (2.8%)		True positive results	70/71 (98.5%)
Cancer associated thrombosis	13 (18 %)					True negative results	1/71 (1.4%)
Antiphospholipid syndrome	5 (6.9%)						
Atrial fibrillation	1 (1.3%)						
Total patient number	71 (100%)						

Table 1

CONCLUSIONS

The test results demonstrate at least 98% correct positive and correct negative results for DOACs, confirming previously published data . It consists an easy and rapid , usually non invasive to perform test and the results can be interpreted by comparison with a predefined color scale. It is an easily repeatable test at any time without technical equipment, identifying the type of anticoagulant even in non-communicating patients. This ongoing study will provide more data in order to validate the use of this device as an easy-to-use , accurate tool in assessing DOAC treatment

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