53 Congresso Nazionale
SIBioC 2021
La Medicina di Laboratorio nella Medicina di Prossimità:
telemedicina, ruoli e competenze

VIRTUAL EDITION
11-13 ottobre 2021

Rapid detection of exposure to direct oral anticoagulants: A qualitative urinary dipstick point-of-care assay

• **M. Marchetti** [1], C. Ambaglio [1] , E. Sanga [1], L. Barcella [1], F. Schieppati [1] , J. Harenberg [2], A. Falanga [1,3]

- UOC Immunoematologia e Medicina Trasfusionale, ASST Papa Giovanni XXIII, Bergamo, Italy
- Ruprecht Karls University of Heidelberg, Heidelberg, Germany
- School of Medicine & Surgery, University of Milano Bicocca, Milano, Italy

INTRODUCTION

- Knowing whether a patient has been recently exposed to direct oral anticoagulants (DOAC) is a very important issue in emergency setting for rapid clinical decisions.
- Chromogenic/ coagulation methods for DOAC measurement on plasma samples have several limitations, including limited accuracy, long turnaround time, and are not available in all laboratories.
- The DOASENSE Dipstick allows to:
  - detect the presence of DOACs in urine in one test
  - discriminate between the presence of a direct factor Xa inhibitor (i.e., rivaroxaban, edoxaban, apixaban) or thrombin inhibitor (i.e., dabigatran).

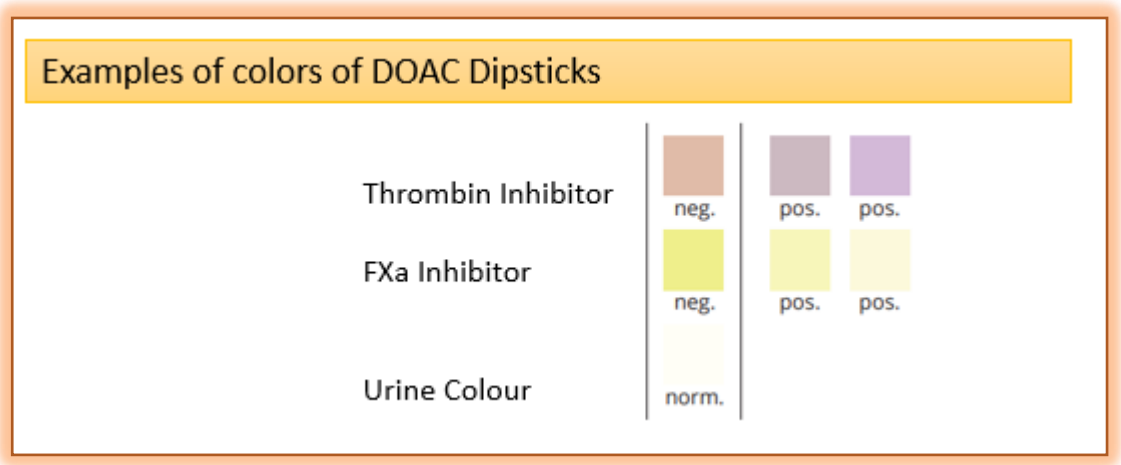
DOACs are excreted at a rate of 30 % to 80 % into urine.

AIM

- Aim of this study was to evaluate the operativity of the DOASENSE Dipstick to implement its use in the Emergency Medicine Service of our Hospital.

METHODS

- **Patients on DOAC** referred to our thrombosis and hemostasis outpatient clinic were included into the study, after providing informed consent. Comorbidities and concomitant therapies were recorded.
- Subjects who were not taking DOACs were also included as negative controls.
- In all subjects, both venous blood and urine samples were collected.
- **Plasma concentration of DOAC** was determined on a Stago STA-R Max® instrumentation.
- **Urine qualitative detection of DOAC** was performed using the DOASENSE Dipsticks and the DOASENSE Reader, that reads out specific colors on the DOAC Dipstick pads, designed to measure direct oral factor Xa inhibitors, direct oral thrombin inhibitors, creatinine, and urine color. Specific colors develop on the pads within 10 min depending on whether the DOAC is present or not.



RESULTS

- A group of 13 patients (11M/2F) on DOACs with a median age of 69 years (range: 22 - 88 years) were studied: 5 patients were on rivaroxaban, 4 on dabigatran, 6 on edoxaban, and 2 on apixaban. In 3 patients, plasma and urinary tests were performed both at the valley and the peak of drug concentration.
- In all urine samples we obtained 100% accuracy. In samples of patients collected at valley (n= 10), the drug was clearly detected in urine, despite the low plasma levels in some of these (range: 13 – 211 ng/ml).
- At eye inspection, only 1 urine was abnormal for color (it was particularly clear and transparent), in this case the DOASENSE reader detected the color anomaly as well as the presence of the DOAC.
- All plasma and urine samples from subjects not on DOACs tested negative.

CONCLUSIONS

- Our study confirmed the high sensitivity and specificity of the urine determination of DOACs by the DOASENSE tool, further supporting its utility at an emergency unit for screening patients with severe bleeding, and/or thrombotic events, or before urgent major surgical interventions.