The Official Journal of the Italian Society for the Study of Hemostasis and Thrombosis
SISET
Società Italiana per lo Studio dell'Emostasi e della Trombosi
Corso Nazionale SISET
Bergamo | 23-25 ottobre 2025

29TH NATIONAL CONFERENCE OF THE ITALIAN SOCIETY FOR THE STUDY OF HEMOSTASIS AND THROMBOSIS, 2025

ABSTRACT N. PO57

DIRECT ORAL ANTICOAGULANT DETERMINATION IN URINE SAMPLES COMPARED TO PLASMA CONCENTRATIONS IN OUTPATIENTS WITH ATRIAL FIBRILLATION AND OBESITY.

A. Pannunzio[1], I.M. Palumbo[1], D. Menichelli[1], V. Cammisotto[2], V. Castellani[3], E. Baldacci[4], R. Mormile[4], A. Chistolini[4], G. Bernardini[5], N. Porcu[1], D. Pastori[2], J. Harenberg[6], F. Violi[2], P. Pignatelli[2].

1 Department of General Surgery, Surgical Specialties and Organ Transplantation "Paride Stefanini", Sapienza University of Roma, Roma; [2]Department of Clinical Internal, Anesthesiological and Cardiovascular Sciences, Sapienza University of Roma, Roma; [3]Department of Translational and Precision Medicine, Sapienza University of Roma; [4]Department of Hematology, Oncology and Dermatology, Sapienza University of Roma; [5]U. O. S. D. Medicina Rigenerativa DAI, Medicina Diagnostica e Radiologia, Policlinico Umberto 1; [6]Ruprecht Karls University of Heidelberg, Heidelberg, Germany.

Background

Obese patients with atrial fibrillation (AF) and high thromboembolic risk need anticoagulant therapy. Few data are available on direct anticoagulants (DOACs) in this population and a point-of-care method has been validated to support rapid clinical decisions and to identify on-off threshold plasma concentrations. The aim of the present study was to evaluate the sensitivity, specificity, positive and negative predictive values (PPV and NPV) of testing for DOACs from urine samples of obese patients taking DOACs for AF.

Methods

Cross-sectional study on obese AF outpatients referring to Policlinico Umberto I of Rome. Inclusion criteria were patients of both sexes, aged ≥18 years, Body Mass Index (BMI) ≥30 Kg/m^2 and receiving a DOAC for AF over at least 7 days. Exclusion criteria were denial of written informed consent, inability to provide a spontaneous urine sample, any contraindication to the administration of DOACs and conditions with known haematuria and blood components such as urobilinogen, which alter the colour of urine and may compromise the interpretation of pad colours of DOAC dipstick. patients were consecutevly enrolled from 2022 to 2024. Trough and peak plasma concentrations and urinary Dipstick were assessed, which determines separate pads for factor Xa (FXA-i) and thrombin inhibitor (THR-i) DOACs. Study endpoints were the sensitivity, specificity, positive and negative predictive values (PPV and NPV) of DOAC Dipstick compared to plasma concentrations. Sub-analysis according to obesity severity and type of DOAC was performed.

The study was approved by the local ethic committee of Sapienza University (No. 0234/2022) and was conducted according to the 1975 Declaration of Helsinki.

Results

320 paired plasma and urine samples were available from 160 enrolled patients (mean age 73.2±9.1 years) see Table 1. Comparing to trough plasma concentrations, DOAC Dipstick showed a sensitivity (mean, 95% confidence interval, CI) of 99.24% (95.82-99.98), specificity of 6.89% (0.85-22.76), PPV 82.80% (81.32-84.18), NPV 66.67% (15.79-95.52) see Table 2. On the other hand, comparing to peak plasma concentrations, DOAC Dipstick showed a sensitivity of 97.8% (93.7-99.5), specificity of 0% (0.0-15.4), PPV of 85.9% (85.6-86.2)

Urinary Dipstick showed a sensitivity of 99.10% (95.4-100.0), specificity of 4.70% (0.60-16.20) and a PPV and NPV of 74.50% (73.2-75.8) and 66.70 (15.7-95.6), compared to plasma thresholds >30 ng/mL of FXA-I and THR-I.

Sub analyses showed similar results between FXA-I and THR-i.

Conclusions

The urine point-of-care has high sensitivity, acceptable PPV, but low specificity and NPV in AF obese patients.

Email: *arianna.pannunzio@uniroma1.it*