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Relationship between DOAC Dipstick test results and quantitative plasma and urine concentrations of DOACs in real-life patient settings – study protocol and case reports

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INTRODUCTION

Rapid and accurate testing for direct oral anticoagulants (DOACs), the direct factor Xa (DXI) and thrombin inhibitors (DTI) is required to facilitate medical decision making in specific emergency and other medical situations. The relationship between these qualitative measurements and quantitative plasma concentrations remains to be determined.

AIM

To investigate whether DOAC Dipstick results can be used to exclude the presence of clinically relevant concentrations of the DXIs apixaban and rivaroxaban and of the DTI dabigatran.

CONCLUSIONS

1) DOAC Dipstick detects both classes of DOACs within 10 min following switching of DOACs and may identify reasons for side effects.
2) Assessment of plasma concentrations of both or only one DOAC class reduces lab tests and may be useful for further medical decision-making.
3) A relationship between plasma and urine concentrations and DOAC Dipstick results will be analysed after termination of the study.
4) DOACs may persist for longer in plasma and urine than expected.

RESULTS

13 patients were treated with rivaroxaban , apixaban and dabigatran (from 15 Sept 2020). The DOAC Dipstick test is easy to perform . Anticoagulation was switched from rivaroxaban to dabigatran in 3 patients for minor bleeding or other minor side effects as decided by the treating physician (Figures 1, 2; Tables 1, 2). After switching, the DOAC Dipstick test detected both DXI and DTI by colour identification of the pads with visual and DOASENSE reader evaluation.

Figure 1: Case 1, visual and reader evaluation of patient's urine

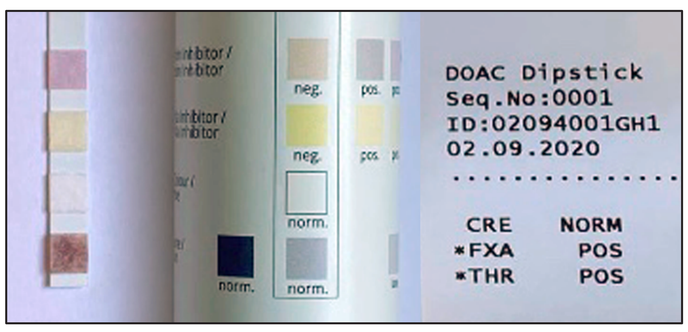

Table 1: Data of patient 1 switching from rivaroxaban to dabigatran

Sample ID	08093001GH1		
Date of birth (year)	1933		
Indication	TIA, low rivaroxaban levels		
DOAC drug and dose	Rivaroxaban 15 mg od, last dose 01.09.20 at 8:30 pm Dabigatran 110 mg bid, first dose 02.09.20, 8:00 pm		
Date/time last DOAC dose	Dabigatran 02.09.20 at 8:00 pm		
Date/time urine collection	03.09.20 at 8:00 am		
Date/time blood drawing	03.09.20 at 8:15 am		
Date/time DOAC Dipstick DOAC concentrations	03.09.20 at 10:00-10:15 am To be determined at end of study		
DOAC Dipstick pads	Observer 1	Observer 2	DOASENSE Reader
Creatinine	normal	normal	normal
DXI	positive	positive	positive
DTI	positive	positive	positive
Urine colour	normal	normal	normal
Creatinine serum (µmol/L)	51 (ref. value 49 - 90 µmol/L)		

Figure 2: Case 2, visual and reader evaluation of patient's urine

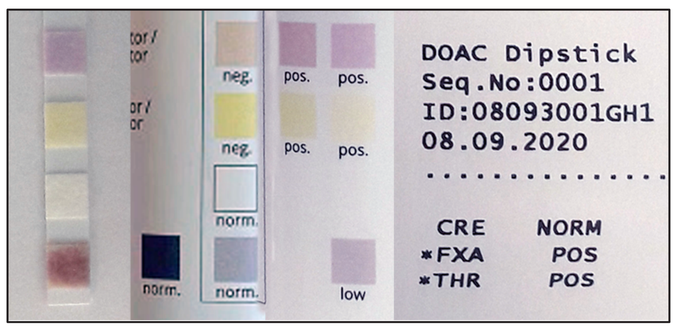

Table 2: Data of patient 2 switching from rivaroxaban to dabigatran

Sample ID	30090450CI1		
Date of birth (year)	1972		
Indication	Atrial fibrillation, cardiomyopathy, interaction with hypertension medication		
DOAC drug and dose	Rivaroxaban 15 mg od, last dose 28.09.20 at 6:00 am Dabigatran 150 mg bid, first dose 29.09.20, at 6:00 am		
Date/time last DOAC dose	Dabigatran .30.9.20 at 8:00 pm		
Date/time urine collection	30.09.20 at 3:00 pm		
Date/time blood drawing	30.09.20 at 3:20 pm		
Date/time DOAC Dipstick DOAC concentrations	30.09.20 at 3.15 to 3:30 pm To be determined at end of study		
DOAC Dipstick pads	Observer 1	Observer 2	DOASENSE Reader
Creatinine	normal	normal	normal
DXI	positive	positive	positive
DTI	positive	positive	positive
Urine colour	normal	normal	normal
Creatinine serum (µmol/L)	116 (ref. value 64 - 104 µmol/L)		

METHODS

This single-centre study aims to compare qualitative DOAC Dipstick results with quantitative plasma and urine measurements in patients (n = between 120 and 180) treated with rivaroxaban, apixaban and dabigatran admitted with neurologic and cardiovascular diseases to general wards of Sestre Milosrdnice University Hospital Center at Zagreb. The DOAC Dipstick test is interpreted by visual colour identification of the pads and by the DOASENSE Reader according to the instructions for use. Biographic data are collected for analysis and comparison with DOAC data. The visual and reader evaluation of DOAC Dipstick pad colours for presence or absence of DOACs is performed independently by two trained medical persons. Concentration of rivaroxaban, apixaban and dabigatran are measured in plasma and urine samples using LC-MS/MS and in plasma samples using specific chromogenic assays and a set of coagulation assays. Data will be analysed at the end of the study.

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