J Thromb Haemost 2013, 11 (Suppl 1) PB 4.45-05

PB 4.45-5

Correctness of the identification by patients of colour of urine samples obtained a point of care test for dabigatran and rivaroxaban

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Background: In certain clinical situation such as for fibrinolytic therapy it may be necessary to know weather patients have a new oral anticoagulants (NOAC) on board or not. Otherwise it makes the decision for a medical intervention difficult. Also, it is important that patients are fully compliant with NOACs, more so than with warfarin, which has a longer half-life. NOACs are excreted between 25% and 80% into the urine and can be determined by point of care (POC) methods. The precision of the POC test is close to 100% for dabigatran (D) and 97% for rivaroxaban (R) when performed by trained medical personal.

Aim: We determined the precision of the reading of the colour of the POC tests by the naked eye of patients because the test will be performed by patients themselves.

Methods: Urine was obtained from 15 patients each during therapy with 110 mg bid or 150 mg bid D or 10 mg od R or no anticoagulation. The presence of NOACs were analysed by the POC tests. These are based on the development of specific colours within 15 min in the presence (positive, blue or clear colour) and absence (negative, green or yellow colour) of D and R, respectively. The colour of the total of 60 samples was identified by the naked eye of 30–32 patients.

Results: A total of 480 and 465 naked eye readings of the colours were available for D and R samples obtained by the POC tests were available for analysis. The results are given as mean and 95% confidence interval (CI), sensitivity, specificity, accuracy, positive (PPI) and negative predictive index (NPI, all%), and the Youden-Index (sensitivity + sensitivity – 100) for D and R. The sensitivity was 100% (99.2–100) and 96.6% (94.5–98.0) for D and R; the specificity was 99.2% (97.9–99.8) and 98.0% (96.1–99.1) for D and R; the accuracy was 99.6% (98.9–100) and 97.2% (95.9–98.2) for D and R; the PPI was 99.2% (97.9–99.8) and 98.3% (96.6–99.2) for D and R; the NPI was 100% (99.2–100) and 96.1% (94.2–98.0) for D and R; and the Youden Index was 0.99 for D and 0.95 for R, respectively.

Conclusion: Patients identify the colours of urine samples obtained by a POC method specific for D and R in urine from patients on treatment with high precision. Patients have to learn testing and identification of colour by expert personal. During this exercise patients with therapy of D with so far unknown very rare amblyopia for red-green colour are identified. For those few patients another person has to perform the POC test. Patients currently perform the test themselves using a prototype test system.