DOAC Dipstick for determination of absence or presence of direct oral anticoagulants and creatinin in urine

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Aim

To determine the usefulness of the in vitro medical device (IVD) DOAC Dipstick in clinical scenarios

Methods and results

- The reagents are immobilized on the surface of the DOAC Dipstick pads.
- The reagents react with urine, specific colours develop according to the action of factor Xa or thrombin on the release of a chromophore bound to a substrate.
- Chromophore release is negatively related to the amount of DOAC in urine and different chromophore colours indicate the absence or presence of factor Xa and thrombin inhibitors on the same test strip.
- Yellow indicates the absence of factor Xa inhibitors and white indicates the presence of factor Xa inhibitors.
- Ochre indicates the absence of thrombin inhibitors and rose indicates the presence of thrombin inhibitors.
- The pad colours can be visually identified as early as 10 min. after incubation of test strip with a urine sample. Pad colours are printed on the test tube for comparison (Fig. 1).

Creatinine (pad 1)

If the colour of pad 1 corresponds to the "normal" (Fig. 2, example A and B) or is between the "norm" or "low" colours (Fig. 2, example C), then creatinine in the urine is normal, indicating normal renal function.

Urine colour (pad 2)

If the pad colour is white like the respective colour marked "norm" on the tube label, then the colours of pads 1, 3, and 4 can be visually evaluated (Fig. 2, examples A, B and C). If the colour of the pad is darker than the colour "norm" on the tube label, the colours of pads 1, 3, and 4 may be falsified (Fig. 3, example D).

Direct oral factor Xa inhibitors (pad 3)

The test pad detects all currently licensed direct oral factor Xa inhibitors, i.e. apixaban, edoxaban, and rivaroxaban. The different inhibitors cannot be distinguished.

Direct oral thrombin inhibitors (pad 4)

If the colour of pad 3 is yellow like the colour marked "neg." (negative) on the tube label, then direct oral factor Xa inhibitors are not present in the urine sample (Fig. 2, example D).

Conclusions

- The qualitative determination of anti-Xa and anti-Xa DOACs by the IVD DOAC Dipstick in urine samples may offer a way for healthcare professionals to detect DOACs in specific patient populations.
- The test results may substantially shorten clinical decision-making.
- The limitations of renal insufficiency and non-normal urine colour are eliminated to detect DOACs in urine by the IVD DOAC Dipstick.

Potential position of IVD DOAC Dipstick in clinical management:

- In a patient with an unknown medication/anticoagulation history, the result obtained with the IVD DOAC Dipstick reduces the number of coagulation assays needed to identify the two types of DOACs from two to one, i.e. factor Xa- or thrombin inhibitors.

Clinical Scenarios

Scenario 1:

Usefulness of DOAC Dipstick in a patient with an acute bleeding event and known or unknown DOAC medication.

Scenario 2:

Usefulness of DOAC Dipstick in a patient about to receive an acute major surgical intervention with known or unknown DOAC medication.

Conflict of interest / address

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