Accuracy of a Rapid Diagnostic Test for the Presence of Direct Oral Factor Xa or Thrombin Inhibitors in Urine—A Multicenter Trial

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Abstract

The rapid determination of the presence of direct oral anticoagulants (DOACs) in a patient remains a major challenge in emergency medicine and for rapid medical treatment decisions. All DOACs are excreted into urine. A sensitive and specific point-of-care test has been developed to determine whether they are present in patient urine samples. This prospective multicenter study aimed to demonstrate at least 95% correct positive and negative predictive results for factor Xa and thrombin inhibitors in urine samples using DOAC Dipstick pads compared with liquid chromatography-tandem mass spectrometry (LC-MS/MS) (NCT03182829). Nine hundred and fourteen subjects were included and 880 were evaluated per protocol (factor Xa inhibitors apixaban, edoxaban, and rivaroxaban: $n = 451$, thrombin inhibitor dabigatran: $n = 429$) at 18 centers. The sensitivity, specificity, accuracy, and predictive values and agreement between methods for determination of factor Xa inhibitors were at least noninferior to 95% with a 0.5% margin and of thrombin inhibitor superior to 97.5%. These results were compared with LC-MS/MS results in the intention-to-analyze cohort (all $p < 0.05$). The receiver operating curve showed *c*-values of 0.989 (factor Xa inhibitors) and 0.995

Keywords

- direct oral anticoagulants
- point-of-care test
- apixaban
- edoxaban
- rivaroxaban
- dabigatran

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