

## Review of DOASENSE Data recently presented at GTH and ISTH DOASENSE GmbH, Heidelberg, 20 September 2021

At the congresses of the German Society for Thrombosis and Haemostasis Research (GTH) and the International Society for Thrombosis and Haemostasis (ISTH), internationally recognized experts presented their new results on the diagnosis of direct oral anticoagulants (DOACs) with DOAC Dipstick from DOASENSE GmbH. In contrast to vitamin K antagonists, there is still no valid evidence for the rapid and reliable detection of DOACs in blood, especially for emergency patients. DOAC Dipstick as urine based point of care test (POCT) remains the only alternative as documented by the summary report of the publications at these two congresses. All reports agree that DOAC Disptick, as a point of care test, provides a valid result on the presence of DOACs in urine within 10 minutes.

Dr. Caspers from Cologne supplemented this with the proof of a time saving obtained from the results of DOAC Dipstick compared to blood tests with specific tests that were carried out at a university clinic where the special laboratory diagnostics are well implemented. Above all, the critical time window of 3 hours from the onset of a stroke could be managed using the DOAC Dipstick but not with laboratory results. This time window is considered to be critical for the rapid therapy decision for lysis or thrombectomy for ischemic stroke.

Cand. med. Andrea Martini from Mannheim presented the results of a meta-analysis of the sensitivity and specificity of the DOAC dipstick. It was able to show that there were no differences between the specific statistical data with the commercial test strips from DOASENSE and those from the development phase at the University of Heidelberg. The development of DOAC Disptick from bench to bedside can therefore be described as successful.

Dr. Sandra Margetić from the University of Zagreb reported on her study protocol on the use of DOAC Dipstick with ischemic stroke and thromboembolic diseases in stable anticoagulated DOAC patients with the aim of defining a comparison with plasma concentrations. The examinations in the first patients with visual evaluation of the colors of the test fields of the test strips were unproblematic and the use of DOASENSE Reader was problem-free and successful. When switching from an oral direct thrombin inhibitor (dabigatran) to an oral factor Xa inhibitor, DOAC Dipstick recorded both types of DOACs at the same time on the two specific test fields. Preliminary results show a low variability between the examiners and to the results with the DOASENSE Reader.

Dr. Rios from Northshore University in USA presented the study protocol in which the plasma concentrations are checked with the results of the DOAC Dipstick from urine in patients

preoperatively before hip replacement for implementation in diagnostics at the clinic. The inclusion of over 300 patients is planned and the study is progressing well despite the restrictions caused by the corona pandemic and we expect data will become available towards the end of 2021.

Dr. Nina Buchtele reported on an ongoing study at the University Clinic Vienna from the emergency department, in which over 300 patients are included. The clinical outcome, the medical measures in these patients with the results of the DOAC Dipstick and the plasma concentrations of apixaban, edoxaban, rivaroxaban and dabigatran was investigated as the primary outcome measure. This study is also making good progress despite certain delays caused by the corona pandemic and will be evaluated in 2021.

Dr. Loula Papageorgiou from Paris presented her study on the plasma concentrations of apixaban and rivaroxaban compared to the qualitative results of DOAC Dipstick in outpatients to check compliance. Over 70 patients have already been included and so far there is a high sensitivity of DOAC Dipstick with a Cut off value of 30 ng / ml plasma.

Dr. van-Horn presented the project of the Karolinska Institute at Stockholm University for the determination of edoxaban in plasma and urine in 50 outpatients. So far, there has been very little experience with this DOAC Almost 40 patients are now included and the evaluation will be carried out in 2021.

In summary, 7 international projects from internationally known centers were presented that address the urgent questions about the use in various medical emergency situations, to check compliance, to answer the question of the plasma concentration of DOACs in relation to a positive and negative result of DOAC dipstick in urine in 2021 get answered