Detection of Direct Oral Anticoagulants in Patient Urine Samples by Prototype and Commercial Test Strips for DOACs – A Systematic Review and Meta-analysis

Andrea Martini1, Job Harenberg2,3, Rupert Bauersachs4, Jan Beyer-Westendorf5, Mark Crowther6, Jonathan Douxfils7,8, Ismail Elalamy9,10, Christel Weiss1, Svetlana Hetjens1

1 Department of Medical Statistics and Biomathematics, Medical Faculty Mannheim, Ruprecht-Karls-University Heidelberg, Mannheim, Germany
2 Ruprecht-Karls-University, Heidelberg, Germany
3 DOASENSE GmbH, Heidelberg, Germany
4 Department of Vascular Medicine, Klinikum Darmstadt GmbH, Darmstadt, Germany
5 Thrombosis Research Unit, Department of Medicine I, Division Hematology, University Hospital “Carl Gustav Carus” Dresden, Dresden, Germany
6 Department of Medicine, McMaster University and Thrombosis and Atherosclerosis Research Institute, Hamilton, Ontario, Canada

Address for correspondence Job Harenberg MD, Professor of Medicine, DOASENSE GmbH, Waldhofer Strasse 102, 69123 Heidelberg, Germany (e-mail: j.harenberg@doasense.de).

7 Department of Pharmacy, Namur Thrombosis and Hemostasis Centre (NTHC), Namur Research Institute for Life Sciences (NARILIS), University of Namur, Namur, Belgium
8 Qualiblood sa, Namur, Belgium
9 Hematology and Thrombosis Centre, Hôpital Tenon, INSERM U938, Sorbonne Université, AP-HP, France
10 I M Sechenov First Moscow State Medical University, Department of Obstetrics and Gynecology, Russia

TH Open 2021;5:e438–e448.

Abstract

The DOAC Dipstick accurately detects the presence or absence of factor Xa (DXI) and thrombin inhibitor (DTI) classes of direct oral anticoagulants (DOACs) in patients’ urine samples on DOAC treatment. The aim of the study was to systematically review the literature and compare the performance of prototype and commercial test strips with a meta-analysis.

A systematic literature search of electronic databases PubMed (MEDLINE) and Cochrane Library was performed. Heterogeneity between studies was calculated using the Chi-squared test and the I² index. A random effects model was used to pool data to compare the performance of prototype and commercial test strips.

Using PRISMA reporting guidelines, four of 1,081 publications were eligible for inclusion in the meta-analysis: three reporting on prototype (DXI n = 658, DTI n = 586) and one on commercial test strips (DXI n = 451, DTI n = 429). Sensitivity and specificity of DXI and DTI detection did not differ significantly between the prototype and commercial test strips. Odds ratios were 0.718 and 0.365 for sensitivity and 1.211 and 1.072 for specificity of DXI and DTI (p-values between 0.3334 and 1.000), respectively. The pooled sensitivity and specificity values for DXI were 0.968 (p = 0.1290, I² 47.1%) and 0.979 (p = 0.1965, I² 35.9%), and for DTI 0.993 (p = 0.1870, I² 37.5%) and 0.993 (p = 0.7380, I² 0%), respectively.

Prototype and commercial DOAC test strips did not differ in their ability to detect DXI and DTI in patient urine samples. This supports the confidence in use of the DOAC Dipstick test, although it needs to be validated in specific patient populations.

Keywords
► meta-analysis
► DOAC Dipstick
► direct oral anticoagulants
► point-of-care test

DOI https://doi.org/10.1055/s-0041-1732437.
ISSN 2512-9465.

© 2021. The Author(s).
This is an open access article published by Thieme under the terms of the Creative Commons Attribution License, permitting unrestricted use, distribution, and reproduction so long as the original work is properly cited.
(https://creativecommons.org/licenses/by/4.0/)
Georg Thieme Verlag KG, Rüdigerstraße 14, 70469 Stuttgart, Germany

Original Article

THIEME

Published online: 2021-09-24

e438