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Consensus statement

Tromboc@t Working Group recommendations for management in patients receiving direct oral anticoagulants[☆]

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ABSTRACT

Background and objectives: In recent years, direct oral anticoagulants (DOACs) have become an alternative to vitamin K antagonists (VKA) for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation (NVAf) as well as for the prevention and treatment of deep venous thrombosis. Pivotal trials have demonstrated non-inferiority and potential superiority compared to warfarin, which increases the options of anticoagulant treatment. In our setting, the anticoagulant treatment units (ATUs) and primary care centres (PCCs) play an important role in the education, follow-up, adherence control and management in special situations of anticoagulated patients. These considerations have motivated us to elaborate the present consensus document that aims to establish clear recommendations that incorporate the findings of scientific research into clinical practice to improve the quality of care in the field of anticoagulation.

Material and methods: A group of experts from the Catalan Thrombosis Group (TROMBOC@T) reviewed all published literature from 2009 to 2016, in order to provide recommendations based on clinical evidence. **Results:** As a result of the project, a set of practical recommendations have been established that will facilitate treatment, education, follow-up and management in special situations of anticoagulated patients with ACODs.

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Conclusions: Progressive increase in the use of DOACs calls for measures to establish and homogenize clinical management guidelines for patients anticoagulated with DOACs in ATUs and PCCs.

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Recomendaciones del Grupo Catalán de Trombosis (Tromboc@t Working Group) para el tratamiento de los pacientes que reciben anticoagulantes orales directos

R E S U M E N

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Antecedentes y objetivos: En los últimos años los anticoagulantes orales directos (ACOD) se han convertido en una alternativa a los antagonistas de la vitamina K (AVK) para la prevención del ictus y embolia sistémica en pacientes con fibrilación auricular no valvular (FANV), así como para la prevención y tratamiento de la trombosis venosa profunda. Los ensayos clínicos han demostrado la no inferioridad y la potencial superioridad en comparación con la warfarina, lo cual permite ampliar las opciones de anticoagulación. En nuestro medio, las Unidades de Tratamiento Anticoagulante (UTA) y los Centros de Atención Primaria (CAP) son los encargados de la educación, seguimiento, control de adherencia y del manejo en situaciones especiales de los pacientes anticoagulados. Estas consideraciones han motivado la preparación del presente documento de consenso, que tiene como objetivo establecer recomendaciones que incorporen los hallazgos de la investigación científica a la práctica clínica para mejorar la calidad asistencial en el ámbito de la anticoagulación.

Material y métodos: Un grupo de expertos del Grupo Catalán de Trombosis (TROMBOC@T) ha revisado la bibliografía publicada entre 2007 y 2016 para poder establecer recomendaciones basadas en la evidencia clínica.

Resultados: Como resultado del proyecto se han establecido un conjunto de recomendaciones de carácter práctico que facilitarán el tratamiento, educación, seguimiento y manejo en situaciones especiales de los pacientes anticoagulados con ACOD.

Conclusiones: El aumento progresivo del uso de los ACOD requiere establecer y homogeneizar las directrices de actuación clínica en el paciente anticoagulado con estos antitrombóticos tanto en las UTA como en los CAP.

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Introduction

The incorporation of direct oral anticoagulants (DOACs) as anti-coagulant drugs has considerably increased the therapeutic arsenal for the prevention of stroke and systemic embolism in patients with non-valvular atrial fibrillation (NVAf), as well as for the prevention and treatment of venous thromboembolic disease (VTD). Unlike vitamin K antagonists (VKA), DOACs can be administered at fixed doses, have few pharmacological interactions, and do not require systematic monitoring. Fundamental studies have shown that they are at least as effective as warfarin in preventing thromboembolic events by decreasing the risk of severe bleeding and intracranial haemorrhage.^{1–8} For some years now, DOACs have been available in our country and the anticoagulant treatment units (ATUs) and the primary care centres (PCCs) use these drugs in their clinical practice. Although there are several national and international documents on their management, there are no clear guidelines on how to perform follow-up, health education and coordinated and interdisciplinary management between ATUs and PCCs in special clinical situations presented by patients while on DOAC therapy. Hence the need to have clear recommendations so that those responsible for antithrombotic therapy can know the results of the different clinical studies.

Objective

The Catalan Group of Thrombosis and Haemostasis (TROMBOC@T), part of the *Catalan Society of Haematology and Hemotherapy* (SCHH), met for the first time in 2015 to create a consensus document with practical recommendations with the aim of standardizing the management of patients anticoagulated with DOAC. The availability of the results of large cohorts of patients obtained

from routine clinical practice and the occurrence of reverting agents in 2016 led to an update of the document in which, among others, the current role of reverting agents was revised and a post-authorization study was launched: «Effectiveness and safety in the use of new generation oral anticoagulants in routine clinical practice: “The Real Life Cohort”; Protocol code: ASO-DAB-2014-01; this project aims to obtain real-life results from our environment.

These guidelines are a summary of the latest update of the TROMBOC@T group consensus document and aims to establish, in a standard way, recommendations that incorporate the findings of scientific research into clinical practice, hence, improving the quality of care in the field of anticoagulation.

Methodology

To obtain a consensus document with the most up-to-date information, we reviewed the studies published in the MEDLINE and EMBASE databases and the abstracts presented at the annual conference of the *American Society of Haematology* (2016). The key words used in the literature search were: *direct oral anticoagulants, atrial fibrillation, venous thromboembolism and treatment*. It was limited to studies carried out on humans between 2007 and 2016 (December). The literature searches focused on randomized controlled trials, but also include registries, non-randomized comparative and descriptive studies, case series, cohort studies, and systematic reviews. The literature references were classified according to the level of evidence (Table 1), following the criteria established by the *US Agency for Health Research and Quality*.⁹ A group of experts from the *Societat Catalana d'Hematologia i Hemoteràpia* and the Catalan Group of Thrombosis and Haemostasis (TROMBOC@T) evaluated all the information collected and established a series of recommendations and therapeutic algorithms

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