

ESC guide on new oral anticoagulant drugs

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A practical guide on the use of the new oral anticoagulants (NOACs) has been produced by the European Heart Rhythm Association (EHRA) of the European Society of Cardiology (ESC). A guide was needed to summarise existing information on different drugs, to answer clinical questions that fall outside what drug companies can legally answer, and to make distinctions between the different drugs.

ESC guidelines on atrial fibrillation recommend the NOACs as preferable to <u>vitamin K antagonists</u> for <u>stroke prevention</u> in patients with non-valvular atrial fibrillation.1 Companies provide a Summary of Product Characteristics (SmPC) for their drug but the content is bound by legal restrictions and the information in SmPCs for different NOACs overlaps.

Professor Hein Heidbuchel (Belgium), lead author of the EHRA guide, said: "Companies are bound by legal restrictions in their SmPCs and for physicians in the field the information is often not specific enough. EHRA goes further than the SmPCs and provides expert guidance, often admittedly based on incomplete data, on what to do in specific clinical situations."

He added: "We have brought together information on all the NOACs in one document so it's clear for physicians what the similarities and differences are. We worked closely with the drug companies to make sure that all of the information in the SmPCs is also in our document."

The paper provides practical advice on how to handle 15 <u>clinical</u>



scenarios. The full paper is published today in EHRA's official journal, *EP-Europace*,2 and the executive summary is published online in *European Heart Journal*.3

The clinical situations include how to initiate and monitor NOAC use, how to measure the anticoagulant effect if needed in specific situations, switching between anticoagulants, ensuring compliance, patients with chronic kidney disease and management of bleeding complications.

NOACs remove the regular monitoring of anticoagulation level that was required for the vitamin K antagonists. But Professor Heidbuchel said: "Compliance is very important for the novel anticoagulant drugs because they have a very short half-life. That means that if you don't take them you will not be protected by <u>anticoagulation</u> and are at greater risk of thromboembolic events."

The document provides tips on how to improve compliance. These include educating patients about the drug's short half-life, and that small minor bleeding such as a nose bleed will stop by itself and patients should continue taking the drug. Compliance can also be improved with a pre-specified follow up scheme.

The guide does not cover the indications for switching from a vitamin K antagonist to a NOAC but it does advise how to switch safely. Professor Heidbuchel said: "We have learned from the big trials that these moments of transitioning from one anticoagulant to another can be dangerous in the sense that patients can be under-anticoagulated."

He added: "The bleeding risk profile of the NOACs is definitely better than that of vitamin K antagonists. Nevertheless bleedings will occur and so our practical document has outlined what action should be taken."

Professor Stefan Hohnloser (Germany), a reviewer of the EHRA guide



and a member of the ESC atrial fibrillation guidelines task force, said: "The updated ESC guidelines on the treatment of atrial fibrillation recommend the NOACs to be used rather than the vitamin K antagonists. Like all new drugs these drugs have pitfalls – for example they are excreted via the kidneys and therefore physicians need to measure renal function regularly. Physicians who follow the practical advice in this guide will dramatically improve the safety of their patients."

More information: References

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- 2. Heidbuchel H, Verhamme P, Alings M, Antz M, Hacke W, Oldgren J, Sinnaeve P, Camm AJ, Kirchhof P. EHRA practical guide on the use of new oral anticoagulants in patients with non-valvular atrial fibrillation. Europace. 2013; 15:625-651, DOI: 10.1093/europace/eut083
- 3. Heidbuchel H, Verhamme P, Alings M, et Al. EHRA practical guide on the use of new oral anticoagulants in patients with non-valvular atrial fibrillation: executive summary. Advance Access published, European Heart Journal.213; DOI: 10.1093/eurhearti/eht134

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