

ESC publishes new guidelines to manage diabetes and CCS

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ESC recommends Rivaroxaban 2.5mg plus aspirin to address patients at high risk of heart attacks, strokes, diabetes and lower extremity arterial disease



The European Society of Cardiology (ESC) has published new clinical practice guidelines on the management of diabetes and 'chronic coronary syndromes (CCS)', which replace the 2013 recommendations for the management of stable coronary artery disease (CAD). The guidelines now recommend that treatment with rivaroxaban vascular dose (2.5 mg twice daily) plus aspirin low dose once daily should be considered in the treatment of patients with chronic coronary syndromes at high risk of further events and low risk of bleeding. Another new ESC guideline addressing diabetes also includes such a recommendation for this regimen in patients with diabetes and lower extremity arterial disease. A new analysis of the COMPASS study published in the Journal of the American College of Cardiology in July this year has demonstrated that patients with high risk factors benefited most from dual pathway inhibition with rivaroxaban and aspirin.

Professor John Eikelboom, Associate Professor, Division of Hematology & Thromboembolism, Department of Medicine, McMaster University, Canada, said: "Chronic coronary syndromes remain a leading cause of morbidity and mortality worldwide. It's a progressive condition that is never stable. Adding new treatment recommendations, including the Class IIa recommendation for rivaroxaban in combination with aspirin, to the updated ESC clinical practice guidelines is therefore a significant step forward in the management of CCS and increases opportunities for patients to benefit from new treatment options."

Adding a second antithrombotic drug like rivaroxaban vascular dose to aspirin is now recommended for patients with multi vessel CAD with at least one of the following risk factors: peripheral arterial disease (PAD), recurrent myocardial infarction, and diabetes mellitus requiring medication or chronic kidney disease (CKD). It is also recommended for patients with a previous myocardial infarction who are at high risk of ischaemic events and have a low risk of bleeding.

In patients with diabetes and chronic symptomatic lower extremity arterial disease - which represents the majority of patients with PAD - without high bleeding risk, the combination of rivaroxaban vascular dose and aspirin should be considered. The ESC guidelines on CCS and diabetes are the first international guidelines to recommend rivaroxaban vascular dose plus aspirin.

The new guidelines also include a change in nomenclature from stable coronary artery disease to CCS. The change reflects the reality that these patients with CCS are at continuous risk for heart attacks and strokes. The underlying

disease status of coronary artery disease, atherosclerotic plaque accumulation, is a dynamic process that can lead to life threatening thrombotic events including strokes and heart attacks, which remain the main cause of death worldwide.

This recommendation is based on data from the Phase III COMPASS study, which showed that rivaroxaban vascular dose plus aspirin 100 mg once daily reduced the composite risk of stroke, cardiovascular death and heart attack by 24% (relative risk reduction) compared with aspirin 100 mg once daily alone in patients with CAD or PAD, including a 42% relative risk reduction in stroke and an 18% mortality reduction. The Phase III randomized controlled COMPASS study was published in 2017, after it was stopped one year ahead of schedule due to overwhelming efficacy.

"We are pleased to see that the ESC recognizes the benefits that adding rivaroxaban 2.5 mg twice daily on top of aspirin can bring to patients and included the treatment in its updated 2019 guidelines just two years after the COMPASS study was published," said Dr Michael Devoy, Head of Medical Affairs & Pharmacovigilance of Bayer AG's Pharmaceuticals Division and Chief Medical Officer.

The guidelines also emphasize the crucial role of healthy lifestyle behaviors, medication and other preventive actions in decreasing the risk of subsequent cardiovascular events and mortality.