

Systematic review with meta-analysis: the risk of major gastrointestinal bleeding with non-vitamin K antagonist oral anticoagulants

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Abstract

Background

Gastrointestinal (GI) bleeding is a common complication among anticoagulated patients. Non-vitamin K antagonist oral anticoagulants (NOACs) are associated with increased risk of GI (major and clinically relevant non-major) bleeding. However, more information is needed regarding severe events.

Aim

To evaluate the risk of NOACs major GI bleeding.

Methods

We searched for phase III randomised clinical trials (RCT) evaluating NOACs (apixaban, dabigatran, edoxaban and rivaroxaban) and reporting major GI bleeding events, in MEDLINE, Cochrane Library, SciELO collection and Web of Science databases (July 2015). Meta-analysis was performed to estimate risk ratio (RR) and 95% confidence intervals (95% CIs). Heterogeneity was assessed with the I(2) test.

Results

A total of 23 studies were included. Among patients with atrial fibrillation, the risk of major GI bleeding was not different between NOACs and vitamin K antagonists (VKA) (RR 1.08, 95% CI 0.85-1.36, I(2) = 78%; 5 RCTs) or acetylsalicylic acid (RR 0.78, 95% CI 0.36-1.72; 1 RCT). Similar results were found for patients undergoing orthopaedic surgery and those with venous thromboembolism. NOACs were not found to increase the risk compared to low-molecular-weight heparin (LMWH) alone (RR 1.42, 95% CI 0.55-3.71, I(2) = 7%; 8 RCTs), the sequential treatment with LMWH-VKA (RR 0.77, 95% CI 0.49-1.21, I(2) = 43%; 7 RCTs) or placebo (RR 1.48, 95% CI 0.15-14.84, I(2) = 21%; 2 RCTs).

Conclusion

Despite previous evidence supporting the association of non-vitamin K antagonist oral anticoagulants and overall GI bleeding, non-vitamin K antagonist oral anticoagulants are not associated with increased risk of major GI bleeding compared to other anticoagulant drugs (with known increased risk of these events).

