Efficacy and Safety of Prolonged Edoxaban Treatment for Patients with Gastrointestinal Cancer Who Have Isolated Distal Deep Vein Thrombosis: Insight from the ONCO DVT Study

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BACKGROUND AND AIMS

Patients with gastrointestinal (GI) cancer could be at high risk of bleeding with anticoagulation therapy involving direct oral anticoagulants. The ONCO DVT study[1] revealed that 12-month edoxaban treatment for patients with cancer and isolated distal deep vein thrombosis (DVT) reduced the composite outcome of symptomatic recurrent venous thromboembolism (VTE) or VTE-related death compared with 3-month edoxaban treatment. However, whether these results are applicable to patients with GI cancer has been uncertain.

The purpose of this post-hoc subgroup analysis was to evaluate the efficacy and safety of 12-month edoxaban treatment for patients with GI cancer.[2]

METHODS

The ONCO DVT study was an RCT that randomly assigned patients with cancer and isolated distal DVT to receive either 12-month or 3-month edoxaban treatment in a 1:1 ratio and evaluated clinical outcomes at 12 months. In the current study, 601 patients were stratified into GI cancer (N=102) and non-GI cancer (N=499) subgroups. GI cancer was defined as oesophageal, gastric, duodenal, small intestine, caecal, or colon cancer. The primary endpoint was a composite outcome of symptomatic recurrent VTE or VTE-related death at 12 months. The major secondary endpoint was major bleeding at 12 months.

RESULTS

Patients with GI cancer were older (73.4 years versus 70.3 years; p=0.004) and there was a higher proportion of men (38% versus 26%; p=0.01) compared with those without. There was no significant difference in body weight, symptoms at baseline, site of thrombus, or dosing of edoxaban between the two subgroups. There was also no significant difference in cancer status including metastatic disease. In the GI cancer subgroup, the primary endpoint did not occur in the 12-month edoxaban group, and occurred in 3/53 (5.7%) patients in the 3-month edoxaban group. In the non-GI cancer subgroup, the primary endpoint occurred in 3/247 (1.3%) patients in the 12-month edoxaban group, and in 19/252 (7.5%) patients in the 3-month edoxaban group (odds ratio [OR]: 0.15; 95% CI: 0.04–0.45). There was no significant interaction in the primary endpoint (interaction p=0.38). In the GI cancer subgroup, the major secondary endpoint occurred in 3/49 (6.1%) patients in the 12-month edoxaban group, and in 4/53 (7.6%) patients in the 3-month edoxaban group (OR: 0.80; 95% CI: 0.15–3.81). In the non-GI cancer subgroup, the major secondary endpoint occurred in 25/247 (10.1%) patients in the 12-month edoxaban group, and in 18/252 (7.1%) patients in the 3-month edoxaban group (OR: 1.46; 95% CI: 0.78–2.79). There was also no significant interaction in the major secondary endpoint (interaction p=0.48).

CONCLUSION

In patients with cancer-associated isolated distal DVT, those with GI cancer did not show signals of an increased risk of major bleeding with prolonged anticoagulation therapy of edoxaban.

References

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