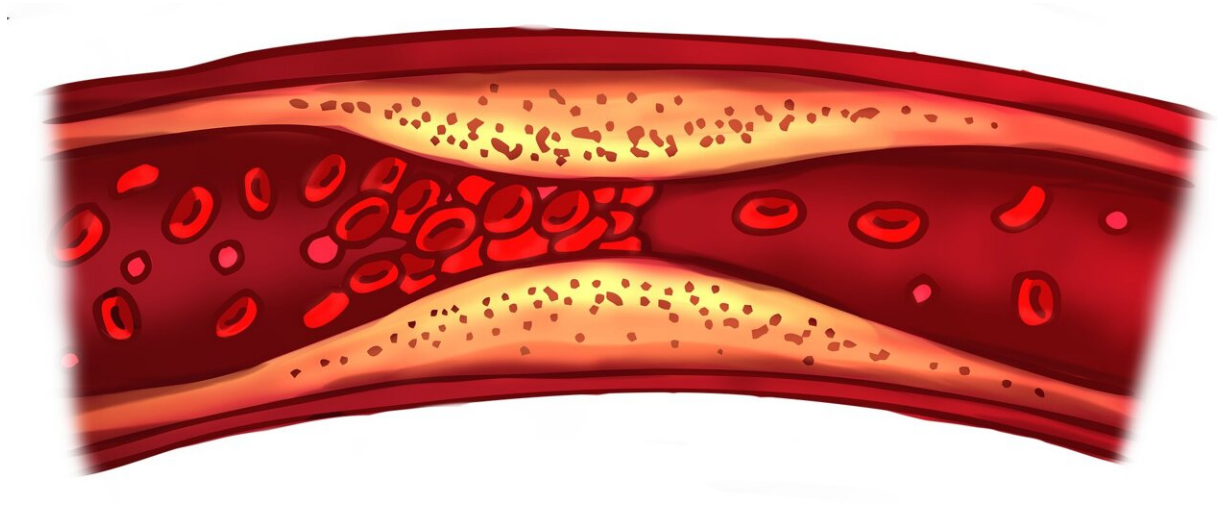
12 months of anticoagulation found to improve outcomes in cancer patients with minor blood clots

August 28 2023



Credit: Pixabay/CC0 Public Domain

Twelve months of edoxaban is superior to three months for the reduction of thrombotic events in patients with cancer and distal deep vein thrombosis (DVT), according to late breaking research presented in a Hot Line session today at ESC Congress 2023.

The mainstay of treatment for DVT is anticoagulation therapy. However, optimal anticoagulation strategies for cancer patients with isolated distal DVT are not currently established. ONCO DVT was the first

randomized trial to compare two different treatment durations of the oral factor Xa inhibitor edoxaban for isolated distal DVT in patients with cancer.

The multicenter, open-label, adjudicator-blinded, superiority trial was designed to compare treatment with 12 months versus 3 months of edoxaban. The trial enrolled patients with active cancer and newly diagnosed isolated distal DVT. The diagnosis of DVT was confirmed with compression ultrasonography. Patients were excluded if they were taking anticoagulation therapy at the time of randomization, had a contraindication to edoxaban, were expected to have a prognosis of three months or less, or had pulmonary embolism.

From April 2019 through June 2022, a total of 604 patients were included from 60 institutions in Japan. The average age of participants was 70.8 years, and 433 patients (72%) were women. The most frequent site of cancer was the ovaries (14%), followed by the uterus (13%), lung (11%), colon (9%) and pancreas (8%). The remaining cancer types included stomach (5%), blood (5%) and breast (5%).

Patients were randomized in a 1:1 fashion to 12 months of edoxaban or 3 months of edoxaban. Edoxaban was administered orally at a fixed dose of 60 mg once daily, or at a lower dose of 30 mg once daily in patients with a creatinine clearance of 30 to 50 mL/minute, or a body weight of 60 kg or less, or in those receiving concomitant treatment with a P-glycoprotein inhibitor.

The primary endpoint was symptomatic recurrent venous thromboembolism (VTE) or VTE-related death event at 12 months. The secondary endpoint was a major bleeding event defined according to the International Society on Thrombosis and Haemostasis (ISTH) criteria at 12 months.

The primary endpoint occurred in 3 of 296 patients (1.0%) in the 12-month edoxaban group and in 22 of 305 patients (7.2%) in the 3-month edoxaban group (odds ratio [OR], 0.13; 95% confidence interval [CI], 0.03 to 0.44). Major bleeding occurred in 28 of 296 patients (9.5%) in the 12-month edoxaban group and in 22 of 305 patients (7.2%) in the 3-month edoxaban group (OR, 1.34; 95% CI, 0.75 to 2.41). Prespecified subgroup analyses according to age, body weight and renal function did not affect the estimates on the primary endpoint.

Principal investigator Dr. Yugo Yamashita of Kyoto University, Japan said, "In cancer patients with isolated distal DVT, 12 months of edoxaban treatment was superior to 3 months with respect to the composite outcome of symptomatic recurrent VTE or VTE-related death with no difference in the rate of major bleeding."

"This is the first and only randomized trial to show the superiority of longer duration over shorter duration of anticoagulation therapy for reducing thrombotic events in cancer patients with isolated distal DVT. We expect that the results will change practice and clinical guidelines in the cardio-oncology field."

Provided by European Society of Cardiology

Citation: 12 months of anticoagulation found to improve outcomes in cancer patients with minor blood clots (2023, August 28) retrieved 13 May 2024 from https://medicalxpress.com/news/2023-08-months-anticoagulation-outcomes-cancer-patients.html