

CARAVAGGIO study: Eliquis as good as heparin for the treatment of cancer-associated venous thrombo-embolism

The CARAVAGGIO trial, an Investigator Sponsored Study supported by Bristol Myers Squibb and Pfizer, found that the oral anticoagulant Eliquis (apixaban) was non-inferior to dalteparin, a low molecular weight heparin given by injection, for the treatment of cancer-associated venous thromboembolism (VTE) and didn't increase the risk of major bleeding. Those results were presented on March 29th by Professor Giancarlo Agnelli from the CARAVAGGIO study during the virtual 2020 meeting hosted by the American College of Cardiology and the World Congress of Cardiology (ACC.20/WCC).

VTE is the second most prevalent cause of death in cancer. Patients with active cancer are indeed at significantly increased risk for blood clots and VTE compared to the general population. Experts say there are many reasons why cancer patients are more susceptible to clotting: the cancer itself can increase the blood viscosity, many cancer therapies are thrombogenic and surgeries can inflame blood vessels and limit patients' movement so clots can form more easily. Therefore, specific studies such as CARAVAGGIO regarding cancer patients and VTE are clearly needed.

CARAVAGGIO was a randomized, open label, controlled clinical trial examining whether oral treatment with Eliquis (apixaban) is non-inferior to subcutaneous dalteparin for the treatment of acute proximal deep vein thrombosis and/or pulmonary embolism in patients with cancer. The trial enrolled 1,170 patients with an active cancer associated VTE at the time of diagnosis at 119 sites in nine European countries, Israel and the U.S. Both treatments demonstrated the same efficacy and safety with a 3.8% rate of major bleedings for apixaban compared to 4.0% with dalteparin (hazard ratio, 0.82; 95% CI, 0.40 to 1.69; p= 0.60). Furthermore, apixaban use was not associated with an increased risk of major gastro-intestinal (GI) bleedings compared to dalteparin (1.9 vs. 1.7%).

"To date, this is the only trial in cancer-associated thrombosis where a DOAC (direct-acting oral anticoagulant) is not associated with increased GI bleeding, in spite of the inclusion of a substantial proportion of GI cancers," Prof. Agnelli said. Interestingly, Prof. Agnelli also reported that apixaban was more effective than dalteparin at preventing recurrent VTE in patients younger than age 65. Several subgroup analyses will be conducted now by Prof. Agnelli's team to determine if certain patients benefit more from one approach.

Given the risk and medical complexities involved in treating cancer patients, the BMS-Pfizer Alliance is committed to supporting independent clinical research, such as CARAVAGGIO, that furthers scientific knowledge and has the potential to advance patient care. Bristol Myers Squibb and Pfizer supported this Investigator Sponsored Research but neither had any role in study design, conduction, data collection or analysis. Therefore, the credits for these results go to Dr. Giancarlo Agnelli, MD, professor of internal medicine at the University of Perugia, Italy, and lead author of this investigator-initiated trial, to his team and to all the investigators of CARAVAGGIO.

Please find [more information in this press release](#) by the American College of Cardiology (ACC).

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