PATIENTS WITH VTE AND CANCER

Analysis of data from treating with Eliquis findings released

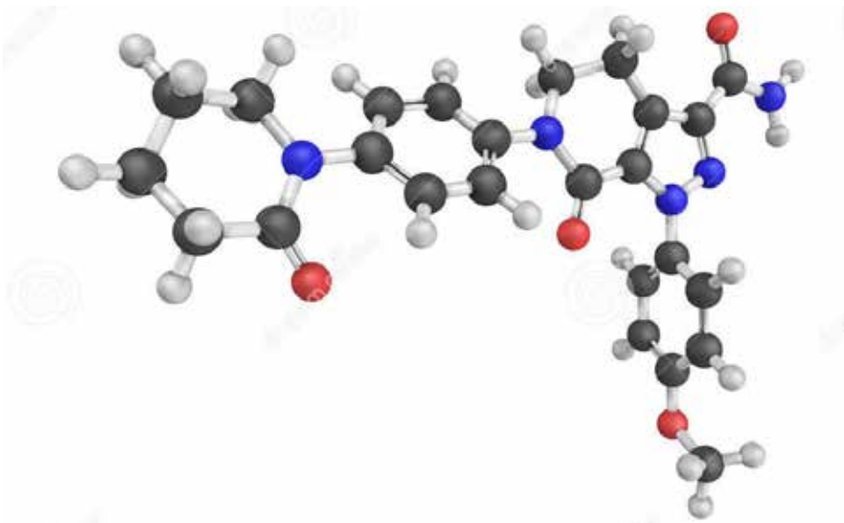
The Bristol-Myers Squibb-Pfizer Alliance has announced results from retrospective real-world data analyses reporting outcomes on the safety and effectiveness of Eliquis® (apixaban) compared to low molecular weight heparin (LMWH) or warfarin for the treatment of venous thromboembolism (VTE) in patients with active cancer (n=14,086).

The real-world data analyses were highlighted during oral presentations at the American Society of Hematology (ASH) Annual Meeting in Orlando, Florida.

Results from the primary analysis showed that Eliquis use was associated with lower rates of major bleeding (MB) (hazard ratio [HR]: 0.63, 95% confidence interval [CI]: 0.47-0.86, p=0.003), clinically-relevant non-major (CRNM) bleeding (HR: 0.81, 95% CI: 0.70-0.94, p=0.006) and recurrent VTE (HR: 0.61, 95% CI: 0.47-0.81, p=0.001) compared to LMWH.

Eliquis was also associated with a lower rate of recurrent VTE (HR: 0.68, 95% CI: 0.52-0.90, p=0.007) and similar rates of major bleeding (HR: 0.73, 95% CI: 0.53-1.0, p=0.051) and CRNM bleeding (HR: 0.89, 95% CI: 0.77-1.04, p=0.145) compared to warfarin. Outcomes were defined based on diagnosis codes and setting of care.

In a second oral presentation, results from a sub-group analysis of the primary study were highlighted based on different levels of risk for developing recurrent VTE, a blood clot most often found in the legs or lungs. Study findings were generally consistent with the primary analysis. It is important to note that, anticoagulants, including Eliquis, increase the risk of bleeding and can cause serious, potentially fatal bleeding.



Third structure of Apixaban, an anticoagulant for the treatment of venous thromboembolic events.

"Real-world evidence analyses such as this have the potential to provide additional insights into complex patient populations such as those with VTE and active cancer," said Alexander Cohen, MD, consultant physician, in the Department of Hematology at Guy's and St. Thomas' NHS Foundation Trust.

"Results from these analyses are a welcomed addition to the growing body of data around recurrent VTE in patients with active cancer," Dr. Cohen said.

VTE is the third most common cause of vascular death after heart attack and stroke.1 VTE can be a major health problem among patients with cancer, with studies showing that patients with cancer are at a significantly increased risk for VTE compared to those without cancer.2 VTE is also a leading cause of death in cancer patients, and a significant predictor for all-cause mortality.3,4

In these real-world analyses, four U.S. commercial insurance claims databases were used to identify VTE patients with active cancer (defined as cancer diagnosis or cancer treatment [chemotherapy, radiation and/or cancer-related surgery] within six months before or 30 days after VTE diagnosis) who initiated apixaban, LMWH, or warfarin within 30 days following the first VTE event.

The risk of events was evaluated using a Cox proportional hazard model. Inverse probability treatment weighting (IPTW) was used to balance patient characteristics between apixaban, LMWH, and warfarin cohorts. Patients were followed to the earliest of: health plan disenrollment, death, index therapy discontinuation, switch to another anticoagulant, study end, or a maximum of 6 months.

This was done to evaluate the rates of MB, CRNMB, and recurrent VTE (fatal or non-fatal) among VTE patients with active cancer prescribed apixaban, LMWH, or warfarin in routine clinical practice.

"Cancer and VTE are closely linked. Patients with cancer have shown to be at increased risk of developing a blood clot," said Roland Chen, MD, vice president, head of Clinical Development, Innovative Medicines at Bristol-Myers Squibb.

"Given this risk and the medical complexities in patients with active cancers, it is important to increase awareness of symptoms related to VTE and bolster the visibility of this patient population to help improve health outcomes."

Real-world data have the potential to complement randomized, controlled clinical trial data by providing additional information about how a medicine performs in routine

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STAINING
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In most patients, staining will subside in 3-6 months. Patients with skin types 4-6 may take up to a year to resolve and this may be due to increased melanocyte production as well as iron deposition secondary to an inflammatory response.

Staining can be treated with heat modalities, although this can be somewhat limited in effectiveness. Lopez, et al, 2001, concluded that weekly subcutaneous administration of DM 500 mg reduces the time to depigmentation by 82 percent in patients with post-sclerotherapy hyperpigmentation. This is rarely needed but can be considered in patients with severe persistent staining.

(See Fig. 1, page 22)

Ronald Bush, MD, FACS, has found with histological examination that patients with staining may have in the treated vessel or in the reticular dermis hemosiderin deposition. This is usually cleared by macrophages and there may also be leukocytes in the area, which is indicative of an inflammatory response. Staining is iron pigment that occurs after red cell lysis.

(See Fig. 2)

TIPS TO AVOID STAINING

Use the lowest concentration of sclerosant when injecting veins and this includes foam sclerotherapy. Empty the spider vein with manual compression after injection and prevent refilling if possible. Flushing with bacteriostatic water may also be helpful. Consider using subdermal tumescent to reduce the lumen size during the post treatment period.

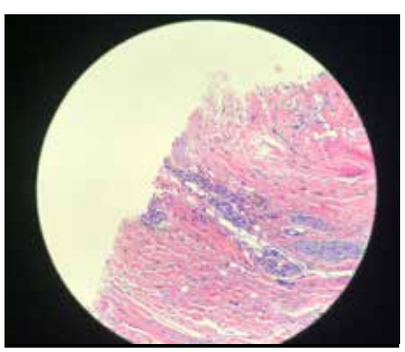

Figure 2 Staining slide

Cosmetically, staining is unacceptable to patients. Plant-based creams may be helpful, especially products that contain licorice root extract oil. Licorice root extract is nature's most potent lightener. The extract from the licorice root is naturally high in glabridin and this chemical inhibits tyrosinase.

Other complications and treatment will be discussed at the March 18 Aesthetic Vein Course at Venous Symposium in New York City. Complete information on the 2020 Venous Symposium is available at venous-symposium.com/ . VTN

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REFERENCES

Lopez L, Dilley RB, & Henriquez, JA. Cutaneous hyperpigmentation following venous sclerotherapy treated with deferoxamine mesylate 2001;(9):795-8.