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POSTER ABSTRACTS

332.THROMBOSIS AND ANTICOAGULATION: CLINICAL AND EPIDEMIOLOGICAL

Efficacy and Safety of Extended Duration Postoperative Thromboprophylaxis with Low-Molecular-Weight-Heparin Among Subgroups of Patients Undergoing Surgical Resection of Colorectal Cancer: A Post-Hoc Analysis of the Periop-01 Trial

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Background: Clinical practice guidelines suggest the use of extended duration of postoperative thromboprophylaxis to prevent venous thromboembolic (VTE) complications after any cancer-related major abdominal or pelvic surgeries. However, recent trials including patients undergoing surgical resection of colorectal cancer have reported relatively low rates of symptomatic VTE. Hence, the risk and benefits of extended postoperative thromboprophylaxis need to be carefully assessed in this patient population. We sought to determine the impact of extended duration thromboprophylaxis with low-molecular-weight-heparin on VTE and bleeding events among different subgroups of patients undergoing surgical resection of localized colorectal cancer.

Methods: This is a pre-planned post-hoc analysis of the PERIOP-01 randomized controlled trial which compared extended (up to 6 weeks) to standard duration (in hospital only) of perioperative thromboprophylaxis with tinzaparin (4500 IU SC daily) in patients undergoing surgical resection of localized colorectal cancer. Subgroup analyses were performed based on different baseline characteristics. The primary efficacy and safety outcomes were objectively documented major VTE and combination of major bleeding (MB) and clinically relevant non-major bleeding (CRNMB) events, respectively. Hazard ratios (HR) with 95% confidence intervals (CI) were calculated using the Cox proportional hazards model to compare the treatment effect accounting for clustering at study center level.

Results: A total of 614 patients were randomized in the PERIOP-01 trial (307 in the extended and 307 in the standard duration thromboprophylaxis groups). Overall, the mean age of the participants was 61 years, 41% of them were women, and most patients were white (90%). Type of primary cancer was well-balanced with 311 patients having rectal cancer (51%), whereas 303 (49%) had primary colon cancer. During the study period, major VTE events occurred in 2% and 1% of the extended- and standard-duration prophylaxis groups, respectively (P=0.8). Combination of MB and CRNMB events occurred in 3% of each group. No specific characteristics were found to be associated with a decreased risk of major VTE among patients on extended duration thromboprophylaxis (Figure 1). Patients with colon cancer resection receiving extended thromboprophylaxis were at an increased risk of bleeding complication compared to patients with rectal cancer (HR 2.57, 95%CI 1.25-5.3) (Figure 1). Other characteristics that may be associated with an increased risk of bleeding among patient on extended thromboprophylaxis included age >= 75 (HR 2.37, 95%CI 0.47-11.98) and male sex (HR 2.13, 95%CI 0.2-23.17), although these characteristics were not statistically significant.

Conclusions: In the PERIOP-01 trial, extended thromboprophylaxis didn't reduce the risk of major VTE in any subgroups of patients. On the other hand, extended duration of thromboprophylaxis may be associated with an increased bleeding risk among male, elderly patients, and those with colon cancer.

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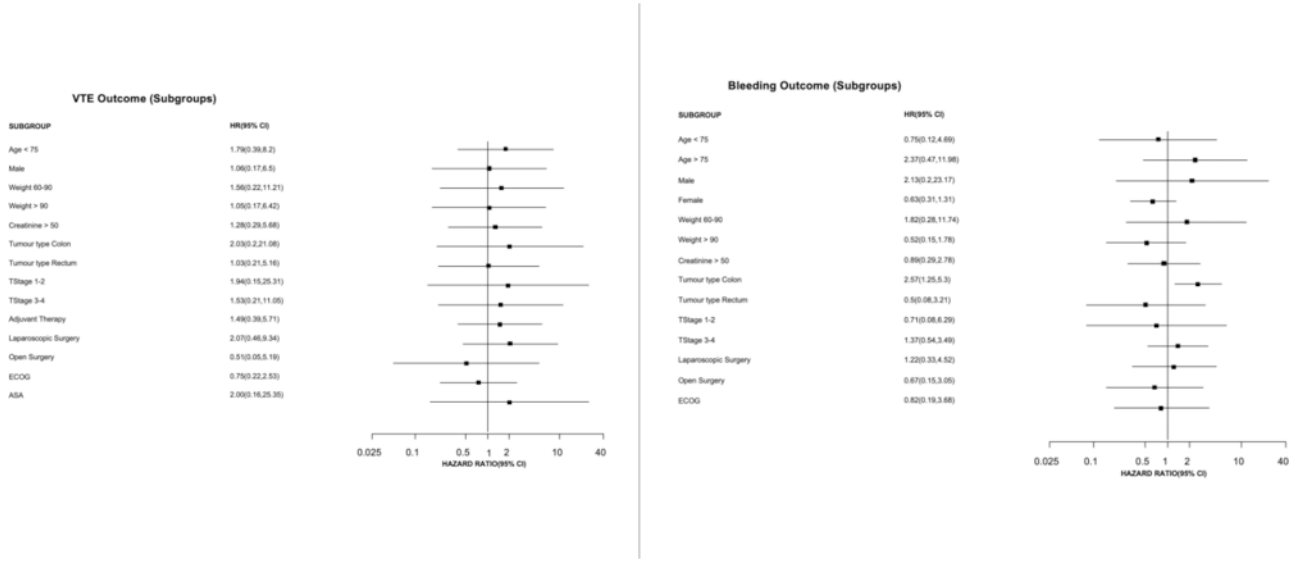

Figure 1

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