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POSTER ABSTRACTS

332.THROMBOSIS AND ANTICOAGULATION: CLINICAL AND EPIDEMIOLOGICAL

All-Cause Mortality after Major Gastrointestinal Bleeding Among Patients Receiving Direct Oral Anticoagulants: A Systematic Review and Meta-Analysis

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Background: Bleeding is the major complication of anticoagulant use, including direct oral anticoagulants (DOACs). Although major gastrointestinal (GI) bleeding represents the single most frequent site of anticoagulant-related bleeding, outcomes after major GI bleeding including mortality are not well characterized and, as a result, severity may be underappreciated with resulting implications for clinical practice. We conducted a systematic review and meta-analysis to quantify the risk for 30-day all-cause mortality after major GI bleeding among DOAC treated patients.
Methods: The systematic review protocol was registered with PROSPERO (CRD42022295815). We searched MEDLINE, EMBASE, and Cochrane CENTRAL from inception to November 26 th, 2021 for studies that met the following inclusion criteria: (i) were randomized controlled trials, or prospective and retrospective cohort studies, (ii) included adults treated with a DOAC for venous thromboembolism (VTE) or atrial fibrillation; and (iii) reported 30-day all-cause mortality after major GI bleeding. Two reviewers independently performed study screening and data extraction in duplicate. Summary estimates for 30-day all-cause mortality were calculated using the random-effects inverse-variance method. Statistical heterogeneity was evaluated using the I^2 statistic and by providing 95% prediction intervals. In a sensitivity analysis, we included only studies that defined major GI bleeding based on the International Society on Thrombosis and Haemostasis (ISTH) criteria. Subgroup analyses were performed according to indication for anticoagulation and type of DOAC. Risk of bias was assessed using a modified version of the QUIPS tool for prognostic studies.
Results: Of 6548 unique studies identified in our search, we included 17 studies which comprised a total of 3910 DOAC-treated patients with major GI bleeds. The pooled estimate of 30-day mortality after a major GI bleed was 9% (95% CI, 7-13%; I^2=76%) (Figure). In a sensitivity analysis, limited to 15 studies (1846 major GI bleeds) that used the ISTH major GI bleeding definition, the pooled estimate of 30-day mortality was 9% (95% CI, 6-13%; I^2=75%; 95% prediction interval, 2-29%). Studies deemed to be at high risk of bias (5 studies, 228 major GI bleeds) had higher mortality (14%; 95% CI, 8-24%; I^2=8%) than those at low risk of bias (11 studies, 3644 major GI bleeds) where mortality was 8% (95% CI, 6-12%; I^2=81%). In patients receiving a DOAC for either VTE or atrial fibrillation (14 studies, 2764 major GI bleeds), the pooled estimate of 30-day mortality was 11% (95% CI, 7-16%; I^2=10%), and in those receiving a DOAC for atrial fibrillation (3 studies, 1119 major GI bleeds), it was 5% (95% CI, 2-14%; I^2=84%). The pooled estimate of 30-day mortality was 9% (95% CI, 6-14%; I^2=80%) in patients on any DOAC (15 studies, 3747 major GI bleeds), 13% (95% CI, 8-20%; I^2=0%) among those on dabigatran (2 studies, 125 major GI bleeds), and 3% (95% CI, 0-13%) among those rivaroxaban (only 1 study, 38 major GI bleeds).
Conclusion: DOAC related major GI bleeding is associated with a significant risk of 30-day mortality. We found substantial heterogeneity across studies which limits the certainty of summary estimates and the ability to compare between DOACs and indications for treatment. Studies reporting on anticoagulation usage should more report on outcomes such as all-cause mortality after bleeding events to better characterize the potential harms of therapy.

Disclosures Siegal: *Servier:* Honoraria, Other: paid indirectly to my institution; *Roche:* Honoraria, Other: paid indirectly to my institution; *BMS-Pfizer:* Honoraria, Other: paid indirectly to my institution; *Astra Zeneca:* Honoraria, Other: paid indirectly to my institution.

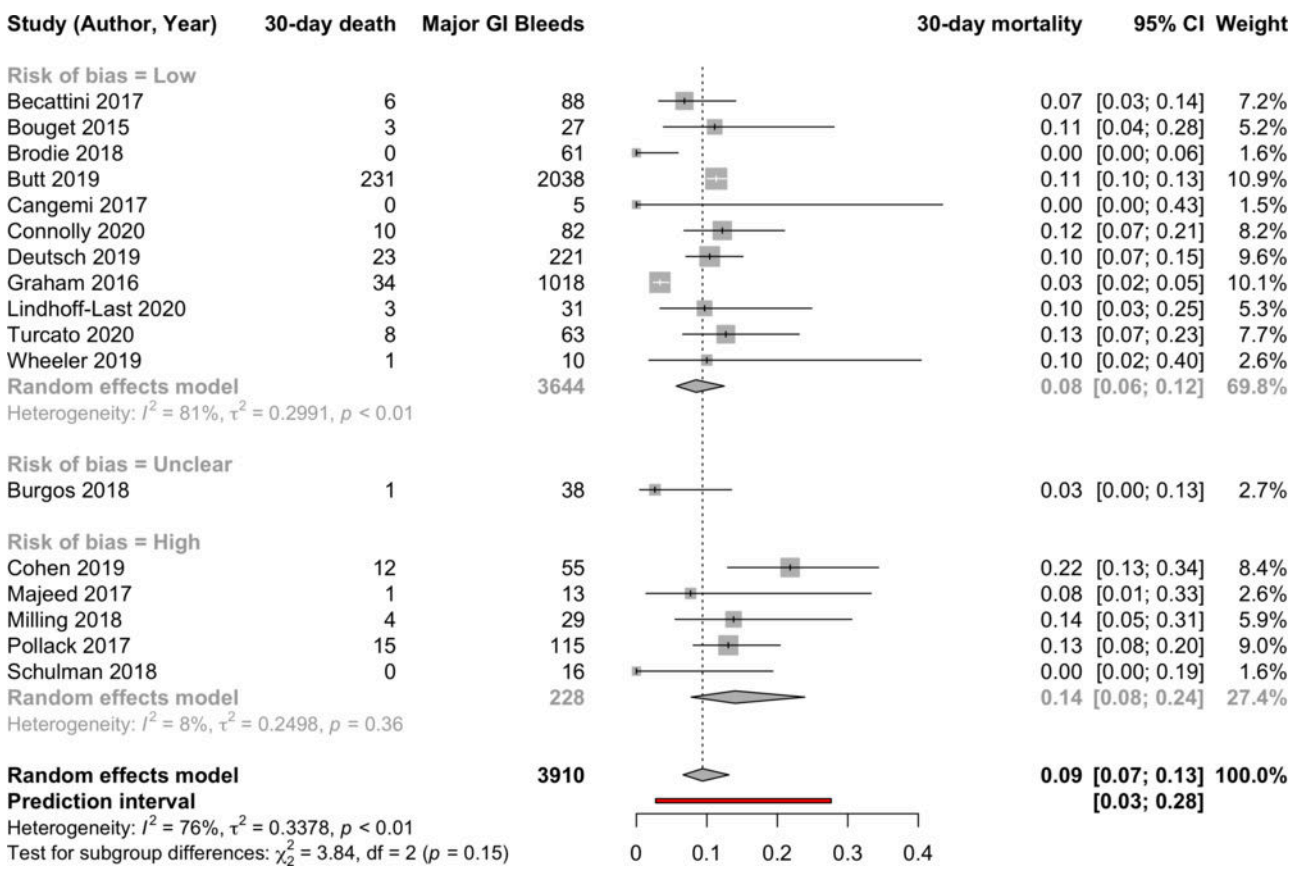

Figure 1

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