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IMPACT OF ECOG PERFORMANCE STATUS ON CANCER-ASSOCIATED THROMBOSIS TREATED WITH DOACS: DATA FROM A MULTICENTER COHORT STUDY

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Background. Data on safety and effectiveness of direct oral anticoagulants (DOACs) in patients with cancer-associated thrombosis (CAT) and impaired functional status is limited. We evaluated the impact of Eastern Cooperative Oncology Group (ECOG) performance status on bleeding and thrombotic events in a real-world cohort.

Methods. Patients with CAT on DOACs were prospectively included in cohorts from six Italian centers and stratified by ECOG status (0-1 vs. 2-4). Primary outcomes were major bleeding (MB) and recurrent venous thromboembolism (VTE); secondary outcome was all-cause mortality. Incidence rates were calculated, and predictors of MB and VTE recurrence were assessed using Cox models within each ECOG subgroup.

Results. Among 817 patients, 702 had ECOG 0-1 and 115 had ECOG 2-4. Patients with ECOG ≥ 2 were older, had worse renal function, and more comorbidities (Table 1). MB occurred at 10.3% vs. 2.8% patient-years (HR 2.92, 95% CI 1.43-5.94) and recurrent VTE at 7.2% vs. 3.6% patient-years (HR 2.16, 95% CI 0.96-4.86) in ECOG 2-4 compared with 0-1 patients. In ECOG 0-1, bleeding was mainly related to anticoagulant treatment, whereas in ECOG 2-4 it was predominantly associated with chronic kidney disease. All-cause mortality occurred at 78.4% patient-years in ECOG 2-4 and 10.5% patient-years in ECOG 0-1 (HR 6.28, 95% CI 4.69-8.41).

Conclusions. Impaired functional status was associated to higher MB and mortality, while VTE recurrence did not differ across groups. Bleeding mechanisms differed by ECOG

status, underscoring the need for individualized anticoagulation. In frail or end-of-life patients, deprescribing and shared decision-making are essential to balance benefit and harm.

Table 1. Baseline features of patients.

Baseline features	ECOG 0-1 (N=702)	ECOG 2-4 (N=115)
Age, years, mean (SD)	65.3 (9.3)	70.8 (10.2)
Age, years, range	24-91	28-93
Male, n (%)	540 (76.9)	91 (78.3)
Weight, kg, mean (SD)	71.2 (16.9)	69.7 (16.2)
BMI (kg/m ²), mean (SD)	25.6 (4.9)	25.7 (5.0)
Systolic hypertension (SBP ≥ 160 mmHg), n (%)	348 (49.6)	53 (46.1)
Diastolic BP (DBP ≥ 95 mmHg), n (%)	101 (14.4)	22 (19.1)
Previous ischemic stroke/TIA/MI, n (%)	29 (4.1)	9 (7.8)
Previous major bleeding, n (%)	25 (3.6)	6 (5.2)
Previous VTE (MI, n (%)	65 (9.3)	9 (7.8)
Liver failure, n (%)	11 (1.6)	10 (8.7)
Acute kidney injury (AKI), n (%)	10 (1.4)	4 (3.5)
ACE-inhibitor use, n (%)	335 (47.7)	53 (46.1)
PE, n (%)	189 (26.9)	15 (13.0)
PE and DVT, n (%)	188 (26.8)	16 (13.9)
Symptomatic VTE (DVT, PE, n (%)	410 (58.4)	63 (54.8)
Ischemic VTE (MI, n (%)	258 (36.8)	27 (23.5)
CANCER SITES		
Gynecological, n (%)	107 (15.3)	12 (10.4)
Bladder, n (%)	104 (14.8)	10 (8.7)
Lung, n (%)	63 (9.0)	28 (24.3)
Colo-rectal, n (%)	61 (8.7)	12 (10.4)
Hematological, n (%)	57 (8.1)	7 (6.1)
Kidney and urinary tract, n (%)	44 (6.3)	9 (7.8)
Prostate, n (%)	31 (4.4)	5 (4.3)
Pancreas, n (%)	22 (3.1)	12 (10.4)
Upper gastrointestinal, n (%)	19 (2.7)	3 (2.6)
Liver and biliary tract, n (%)	12 (1.7)	1 (0.9)
Brain, n (%)	9 (1.3)	3 (2.6)
Melanoma, n (%)	10 (1.4)	1 (0.9)
Thyroid, n (%)	5 (0.7)	1 (0.9)
Other sites, n (%)	29 (4.1)	7 (6.1)
Unknown, n (%)	0 (0)	1 (0.9)

Abbreviations: BMI, body mass index; DOACs, direct oral anticoagulants; DVT, deep vein thrombosis; ECOG, Eastern Cooperative Oncology Group; AKI, acute kidney injury; ACE-inhibitor, angiotensin-converting enzyme inhibitor; SBP, systolic blood pressure; DBP, diastolic blood pressure; MI, myocardial infarction; TIA, transient ischemic attack; VTE, venous thromboembolism.

Note: n, number of missing values among ECOG 0-1 group; h, number of missing values among ECOG 2-4 group.