PREDICTION OF CLINICALLY SIGNIFICANT BLEEDING IN ANTICOAGULATED PATIENTS FOR CANCER-ASSOCIATED VENOUS THROMBOEMBOLISM: VALIDATION OF THE B-CAT SCORE IN A COHORT FROM THE TESEO STUDY

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BACKGROUND

There is a **lack of a validated scoring system for predicting clinically significant bleeding** in patients anticoagulated for **cancer-associated venous thromboembolism (Ca-VTE).**

OBJECTIVES

The aim was to **validate the B-CAT score**, a new tool designed to classify the risk of bleeding in oncology patients receiving anticoagulation.

METHODS

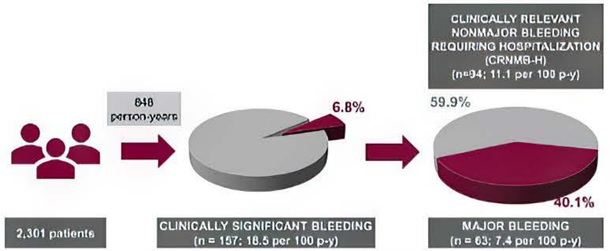
Data came from the **TESEO study, a national, multicenter and prospective** registry that documents **patients with Ca-VTE.** Patients anticoagulated were included and **observed for 180 days for major or clinically relevant bleeding.** Variables of the B-CAT score were selected, except for minor trauma, and minor surgery and clinically relevant bleeding not requiring hospitalization after Ca-VTE, as these were not available. Patients were classified according to bleeding risk into three categories, and **a multivariate logistic regression model** was developed to estimate the risk of bleeding.

RESULTS

BASELINE CHARACTERISTICS (N = 2,301)

		TESEO (n = 2,301)	Cohen et al. (n = 15,749)
Sex	Male	1,153 (50.1%)	7,625 (48.4%)
Age	Median (p25, p75)	65 (58-73)	68 (60-75)
ECOG PS	0 - 1	1,679 (72.9%)	-
	2 - 4	622 (27.1%)	-
Cancer type	Breast	244 (10.6%)	2,906 (18.5%)
	Cervix	29 (1.3%)	144 (0.9%)
	Uterus	51 (2.2%)	379 (2.4%)
	Ovarian	99 (4.3%)	562 (3.6%)
	Prostate	51 (2.2%)	1,639 (10.4%)
	Central nervous system	62 (2.7%)	418 (2.7%)
	Upper gastrointestinal tract	154 (6.7%)	994 (6.3%)
	Colorectal and other low gastrointestinal tract	436 (18.9%)	2,605 (16.5%)
	Hepatopancreatobiliary	292 (12.7%)	677 (4.3%)
	Lung	523 (22.8%)	1,538 (9.8%)
	Kidney	36 (1.6%)	354 (2.2%)
	Bladder	82 (3.6%)	647 (4.1%)
	Hematologic	11 (0.5%)	1,418 (9%)
	Malignant melanoma	22 (1%)	260 (1.7%)
	Head and neck	51 (2.2%)	-
	Other	148 (6.4%)	915 (5.8%)
	Unknown primary site	10 (0.4%)	293 (1.9%)
Metastases		1,628 (70.8%)	7,052 (44.8%)
Cancer therapy	None	76 (3.3%)	3,831 (24.3%)
	Chemotherapy	1,044 (45.4%)	7,905 (50.2%)
	Combination chemotherapy	301 (13.1%)	
	Targeted therapy	79 (3.4%)	-
	Immunotherapy	97 (4.2%)	-
	Hormonal	55 (2.4%)	2,064 (13.1%)
	Other	55 (2.4%)	-
	Not available	594 (25.8%)	-
Radiation		599 (26%)	1,949 (12.4%)
Venous thromboembolism	Deep vein thrombosis of the legs	585 (25.4%)	6,835 (43.4%)
	Pulmonary embolism	1,296 (56.3%)	8,914 (56.6%)
	Other	612 (26.6%)	-
Anticoagulant treatment	Low-molecular-weight heparin	2,238 (97.2%)	10,820 (68.7%)
	Direct Oral Anticoagulant	50 (2.2%)	2,039 (12.9%)
	Vitamin K antagonist	13 (0.6%)	2,890 (18.4%)

CLINICALLY SIGNIFICANT BLEEDING



PREDICTORS FOR SIGNIFICANT BLEEDING

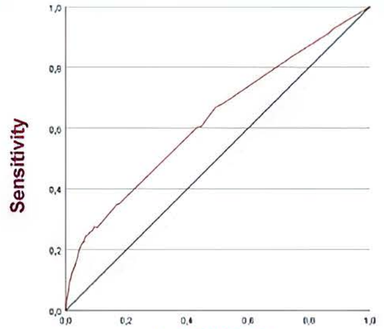
Cancer type	436 (18.9%)
Metastases	1,628 (70.8%)
Minor surgery after Ca-VTE	Not available
Minor trauma	Not available
Major bleeding before Ca-VTE	15 (0.7%)
CRNMB < 731 days before Ca-VTE	31 (1.3%)
CRNMB not requiring hospitalization after Ca-VTE	Not available
Stroke	75 (3.3%)
Gastroduodenal disease	189 (8.2%)
Anaemia	1,216 (52.8%)
Coagulation disorder	20 (0.9%)

BLEEDING RISK ACCORDING TO B-CAT

Score category	Bleeding events, n (%)	Person-years	Incidence rate, events/100 p-y (95% CI)	Cohen et al.
Low-risk group (n=1,101)	51 (4.6%)	449	11.4 (8.3–14.5)	5.12 (4.4–6)
Medium-risk group (n=1,161)	95 (8.2%)	389	24.4 (19.5–29.3)	18.96 (6.9–21.2)
High-risk group (n=39)	11 (28.2%)	11	100 (41–159)	56.64 (44–71.6)

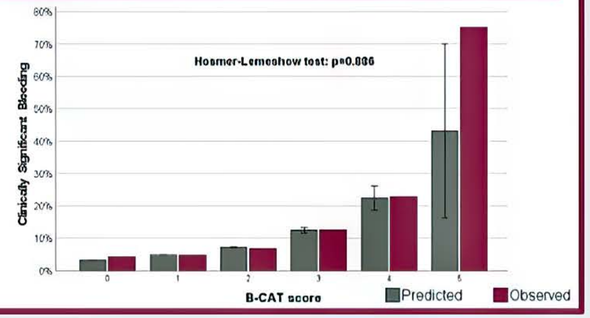
p <0.001

PREDICTIVE MODEL: DISCRIMINATION



	C-statistic TESEO	Cohen et al.
Complete cohort	0.627 (0.578 – 0.675)	0.7 (0.65 – 0.75)
Major bleeding	0.609 (0.531 – 0.687)	0.76 (0.68 – 0.84)
CRNMB-H	0.632 (0.571 – 0.692)	0.67 (0.61 – 0.73)

PREDICTIVE MODEL: CALIBRATION



CONCLUSIONS

We have validated the bleeding risk score B-CAT in patients with Ca-VTE receiving anticoagulation. This model can contribute to standardizing decision-making in a context where quality evidence is limited.

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