which led us to use argatroban and later warfarin for initial HIT treatment and switch to fondaparinux only in later stages of pregnancy.

PB2432 | ETNA-VTE Europe: The Effect of Body Mass Index on 12-Month Outcomes in VTE Patients with Edoxaban

M. Schindewolf[1]; B. Brüggenjürgen[2]; C. Ay[3]; P. Hainaut[4]; U. Hoffmann[5]; S. Gaine[6]; M. Coppens[7]; D. Jiménez[8]; P. Levy[9]; J. López Bastida[10]; E. Vicaut[11]; P. Bramlage[12]; G. Agnelli[13]; A.T. Cohen[14]; ETNA-VTE-Europe Investigators

[1]*University of Bern, Bern University Hospital, Division of Angiology, Bern, Switzerland;* [2]*Steinbeis-University, Institute for Health Economics, Berlin, Germany;* [3]*Medical University of Vienna, Department of Medicine I, Vienna, Austria;* [4]*Cliniques Universitaires Saint Luc, UCL, Department of General Internal Medicine, Brussels, Belgium;* [5]*Medical Clinic IV, University Hospital, Ludwig-Maximilians-University, Division of Angiology, Munich, Germany;* [6]*Mater Misericordiae University Hospital, National Pulmonary Hypertension Unit, Dublin, Ireland;* [7]*Amsterdam University Medical Centers, Department of Vascular Medicine, Amsterdam, the Netherlands;* [8]*Ramón y Cajal Hospital, Madrid, Spain;* [9]*LEGOS, Université Paris - Dauphine, Paris, France;* [10]*University of Castilla-La Mancha, Toledo, Spain;* [11]*Université Paris Descartes, Department of Medicine, Paris, France;* [12]*Institute for Pharmacology and Preventive Medicine, Berlin, Germany;* [13]*University of Perugia, Internal and Cardiovascular Medicine-Stroke Unit, Perugia, Italy;* [14]*King's College London, Guy's and St Thomas' NHS Foundation Trust, London, United Kingdom*

Background: Obesity (defined as a body mass index [BMI] ≥30 kg/m^2) increases the risk for first spontaneous venous thromboembolism (VTE) two-fold. During the treatment of VTE, obesity may also affect bioavailability, distribution, and half-life of edoxaban, and consequently, patient outcomes. Dose reduction of edoxaban is recommended in patients with a bodyweight ≤60 kg.

Aims: To characterize obese patients and to investigate outcomes in patients treated with edoxaban categorised by BMI.

Methods: Patients in ETNA-VTE-Europe who had acute symptomatic VTE and received edoxaban were recruited across eight European countries. Patients were divided according to BMI [kg/m^2]: 18.5-25, 25-30 and ≥30.

Results: Of 2131 patients, 573 were normal weight, 849 overweight (BMI 25-30) and 560 obese (BMI ≥30); 149 patients had no BMI data and 18 patients had a BMI < 18.5. Obese patients were more often female, had higher rates of hypertension and diabetes, chronic venous insufficiency and a higher eGFR than non-obese patients. They also had higher rates of prior VTE and were receiving the 60 mg edoxaban dose more often (Table 1). At 1-year follow up, VTE recurrence was 2.67% and consistent across categories. Any bleeding was observed in 12.29% and major bleeding in 1.69% with no increase with BMI. While all-cause mortality was in the same order across BMI groups, there was a trend for a reduced cardiovascular mortality in obese patients (Table 2). Table 1: Baseli… Table 2: Clinic…

Conclusions: Obesity does not appear to substantially affect the risks of recurrent VTE and any bleeding complications in a contemporary cohort of edoxaban treated patients. Apart from all-cause mortality following a U-shape association and CV-mortality being

TABLE 1 Baseline characteristics of patients enrolled in the ETNA-VTE-Europe study according to BMI [N=2131]*

	Overall*† [N=2131]	BMI 18.5-25* [N=573]	BMI 25-30* [N=849]	BMI ≥30 * [N=560]
Female, n (%)	983 (46.1%)	297 (51.8%)	335 (39.5%)	322 (51.3%)
Age, years, mean ± SD	62.4 ± 16.07	61.9 ± 18.19	64.0 ± 14.93	61.9 ± 14.97
BMI, kg/m^2, mean ± SD	27.9 ± 5.00	22.7 ± 1.85	27.3 ± 1.37	34.2 ± 4.04
recalc. eGFR (Cockroft-Gault), ml/min, mean ± SD	95.7 ± 38.95	82.1 ± 31.85	92.3 ± 34.60	114.0 ± 44.88
Frailty (physician judgement), n (%)	261 (12.2%)	75 (13.1%)	106 (12.5%)	75 (11.9%)
Medical history, n (%)				
Hypertension	888 (41.7%)	165 (28.8%)	359 (42.3%)	60 (57.3%)
Diabetes Mellitus	235 (11.0%)	40 (7.0%)	81 (9.5%)	117 (18.6%)
Chronic venous insufficiency	234 (11.0%)	49 (8.6%)	104 (12.2%)	85 (13.5%)
History of VTE, n (%)				
Prior PE±DVT	160 (7.5%)	38 (6.6%)	55 (6.5%)	54 (8.6%)
Prior DVT	350 (16.4%)	89 (15.5%)	149 (17.6%)	108 (17.2%)
Edoxaban treatment at baseline, n (%)				
Edoxaban 60 mg	1873 (87.9%)	449 (78.4%)	771 (90.8%)	521 (93.0%)
Edoxaban 30 mg	258 (12.1%)	124 (21.6%)	78 (9.2%)	39 (7.0%)

DVT, deep vein thrombosis; eGFR, estimated glomerular filtration rate; PE, pulmonary embolism; SD, standard deviation; VTE, venous thromboembolism. * Patients with history of cancer, active cancer at baseline or new cancer within six months (182 days) after start of acute index VTE were excluded from analysis. †One-hundred forty nine patients had missing BMI.

TABLE 2 Clinical outcomes of patients enrolled in the ETNA-VTE-Europe study during 12-month follow-up according to BMI (N=2131)*

Outcomes during 12-months follow-up*, n (%)	Overall†‡ [N=2131]	BMI 18.5-25† [N=573]	BMI < 25† [N=573]	BMI ≥30† [N=560]
VTE recurrences	57 (2.67%)	14 (2.44%)	24 (2.83%)	17 (2.71%)
PE with or w/o DVT	24 (1.13%)	4 (0.70%)	11 (1.30%)	7 (1.11%)
DVT only	38 (1.78%)	10 (1.75%)	17 (2.00%)	12 (1.91%)
Any bleeding	262 (12.29%)	78 (13.61%)	97 (11.43%)	87 (13.85%)
ICH	8 (0.38%)	1 (0.17%)	5 (0.59%)	1 (0.16%)
Major bleeding [ISTH]	36 (1.69%)	10 (1.75%)	17 (2.00%)	7 (1.11%)
CRNM bleeding	69 (3.24%)	18 (3.14%)	25 (2.94%)	28 (4.46%)
Major GI bleeding	9 (0.42%)	3 (0.52%)	4 (0.47%)	1 (0.16%)
All−cause mortality	46 (2.16%)	17 (2.97%)	15 (1.77%)	15 (2.39%)
CV mortality	23 (1.08%)	9 (1.57%)	9 (1.06%)	5 (0.80%)
Any stroke	13 (0.61%)	3 (0.52%)	4 (0.47%)	5 (0.80%)
Ischaemic stroke	7 (0.33%)	2 (0.35%)	1 (0.12%)	4 (0.64%)
Haemorrhagic stroke	3 (0.14%)	0 (0.00%)	2 (0.24%)	0 (0.00%)
Stroke or systemic embolism	16 (0.75%)	3 (0.52%)	5 (0.59%)	8 (1.27%)

CRNM, clinically relevant nonmajor; CV, cardiovascular; DVT, deep vein thrombosis; GI, gastrointestinal; ICH, intracranial haemorrhage; ISTH, International Society on Thrombosis and Haemostasis; PE, pulmonary embolism; VTE, venous thromboembolism. *Overall population †Patients with history of cancer, active cancer at baseline or new cancer within six months (182 days) after start of acute index VTE were excluded from analysis. ‡One-hundred forty nine patients had missing BMI.

lowest in BMI ≥30, there were no appreciable differences in outcomes across the various subgroups.

PB2433 | Predicting Recurrence and Bleeding in Patients with Venous Thromboembolism: A Systematic Review and Critical Appraisal of Prediction Models

M.A. de Winter[1]; N. van Es[2]; H.R. Büller[2]; F.L.J. Visseren[1]; M. Nijkeuter[1]

[1]*UMC Utrecht, Internal Medicine, Utrecht, the Netherlands;*

[2]*Amsterdam UMC, Vascular Medicine, Amsterdam, the Netherlands*

Background: Currently available prediction models for recurrence and bleeding are infrequently used when deciding about anticoagulant treatment duration after venous thromboembolism (VTE) due to concerns about performance and validity.

Aims: Our aim was to critically appraise these models by systematically summarizing data from model derivation and validation studies in the setting of VTE.

Methods: MEDLINE and CENTRAL were searched up until November 15th, 2019. All studies using a design for developing, updating, validating, or evaluating prediction models for recurrence or bleeding in adult patients with VTE were included. The Prediction model Risk Of Bias Assessment Tool (PROBAST) was used to assess risk of bias and applicability of the included studies.

Results: Search and selection yielded 19 eligible studies evaluating 6 prediction models for recurrent VTE (Table 1), including 6 on model development, 8 on model validation, and 1 on updating an existing model. Four models were evaluated in independent datasets at least once. Overall, models for recurrent VTE appeared to perform poorly to moderately with c-statistics ranging between 0.39 to 0.83. Twenty-seven eligible studies that evaluated 18 prediction models for bleeding during anticoagulant treatment in patients with VTE were identified (Table 1), including 8 studies on model development and 16 on model validation. Although most models seemed promising in development studies, their predictive performance was poor to moderate in external validation studies; c-statistics ranged from 0.52 to 0.72, with the majority being below 0.60. All but two of the included studies were judged to be at high risk of bias, mainly due to limitations in the statistical analysis.

Conclusions: Currently available prognostic models for recurrent VTE and anticoagulation-related bleeding often have important methodological limitations and insufficient predictive accuracy. These findings do not support the use of these models to decide about continuing or discontinuing anticoagulant treatment after initial treatment of VTE.

TABLE 1 Identified prediction models for anticoagulation-related bleeding and recurrent venous thromboembolism

Recurrent VTE		Bleeding			
		Developed in patients with VTE receiving oral anticoagulation		Validated in VTE population	
Models	*External validation studies*	*Models*	*External validation studies*	*Models*	*External validation studies*
L-TRRiP	1	BLLADS	0	ORBIT	1
DAMOVES	1	Seiler	0	ATRIA	4
Huang	0	Hokusai	0	HAS-BLED	7
Vienna (updated)	1	EINSTEIN	0	HEMORR2HAGES	3
DASH	4	VTE-BLEED	4	Shireman	1
Vienna	2	ACCP 2016	1	Kearon	2
HERDOO2	1	ACCP 2012	2	mOBRI	2
		RIETE	8	Nieuwenhuis	1
		Kuijer	6	OBRI	3

Abbreviations: VTE venous thromboembolism