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Original Article

External validation of a prognostic score to identify low-risk outpatients with acute deep venous thrombosis in the lower limbs

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ABSTRACT

Background: Current clinical guidelines suggest home treatment for patients diagnosed with acute deep venous thrombosis (DVT). A prognostic score has been proposed to identify low-risk patients; however, its validation remains limited.

Method: This prospective observational study aimed to externally validate the prognostic score in selecting low-risk outpatients with acute DVT in the lower limbs. Consecutive outpatients diagnosed with acute DVT in a tertiary hospital were included. The score included 6 variables: heart failure, kidney failure, recent major bleeding, altered platelet count, immobilization, and cancer. The primary outcome was the incidence of a composite outcome, including confirmed diagnosis of PE, major bleeding, or all-cause death at 7 days. Patients meeting zero criteria were considered low risk.

Results: Among the 1035 patients included, 485 (46.9 %) met zero criteria. Of these, 0.2 % (95 % CI 0.0–1.1 %) and 0.4 % (95 % CI, 0.0–1.5 %) patients experienced the composite outcome at 7 and 30 days, respectively. Among patients who met 1 or more criteria for admission, 344 patients (62.5 %) were discharged. Among these, the composite outcome at 7 and 30 days occurred in 2 (0.6 %) and 5 (1.4 %) patients, respectively. The C-statistics of the score were 0.68 (95 % CI, 0.57–0.79) and 0.69 (95 % CI, 0.64–0.76) at 7 and 30 days, respectively.

Conclusion: This study demonstrates the efficacy of the prognostic score in identifying low-risk outpatients with acute DVT. It also suggests that a considerable proportion of patients with acute DVT may benefit from outpatient treatment despite having some risk criteria, highlighting the potential for optimizing ambulatory care pathways.

1. Introduction

Deep vein thrombosis (DVT) and pulmonary embolism (PE) stand as the primary manifestations of venous thromboembolism (VTE) [1-3]. Nonetheless, the absence of national surveillance systems for VTE leaves the exact number of affected individuals unknown [4]. Studies based on clinical-administrative and hospital database suggest an estimated annual incidence of VTE ranging from 1 to 1.8 per 1000 inhabitants in Europe. Although the presentation varies across studies, they concur that over 50 % of VTE cases manifest as isolated DVT, while the remainder present as PE (with or without DVT) [5].

Anticoagulant therapy during the initial phase is recommended for a minimum duration of 3 months for all patients with acute VTE [6,7]. Over recent decades, the prognosis for VTE patients has shown improvement. Early mortality (within the first 30 days) in DVT has decreased from 3.9 % (during the period 2001–2005) to 2.7 % (during the period 2010–2014) [8]. The primary concern associated with anticoagulant therapy is bleeding, which can potentially be fatal [9], with the highest risk observed during the initial 7 days of treatment [10]. Early major bleeding in DVT occurs in 0.1 % of cases [8]; however, the

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bleeding risk is contingent on the type of anticoagulant therapy employed. Direct oral anticoagulants (DOACs), in comparison to vitamin K antagonists (VKAs), exhibit a lower risk of major, fatal, and intracranial bleeding [11,12].

A Cochrane review published in 2018 included seven clinical trials involving 1839 patients diagnosed with DVT in the emergency department (ED). These trials evaluated the safety and efficacy of home versus hospital treatment, where DVT was managed with low molecular weight heparin (LMWH) or unfractionated heparin (UFH). The evidence suggests that home treatment is associated with a decrease in recurrent VTE, with no differences in mortality or major bleeding [13].

With the enhanced prognosis of patients and the advent of direct oral anticoagulants, current clinical guidelines advocate for the outpatient treatment of patients diagnosed with DVT in the ED who have suitable home circumstances, rather than admission [7]. However, a 2014 study revealed that fewer than 50 % of patients received home treatment [14]. Consequently, Trujillo-Santos et al. [15] introduced a score in 2015 using data from the Registro Informatizado de Enfermedad Tromboembólica (RIETE) registry comprising 6 variables: chronic heart failure, creatinine clearance <60 ml/min, recent major bleeding, platelet count <100,000/mm3 or >450,000/mm^3, immobilization for ≥4 days, and active cancer. Patients meeting zero criteria were categorized as low risk for complications (PE, major bleeding, or death) within the initial 7 days. As of now, this score has not been validated.

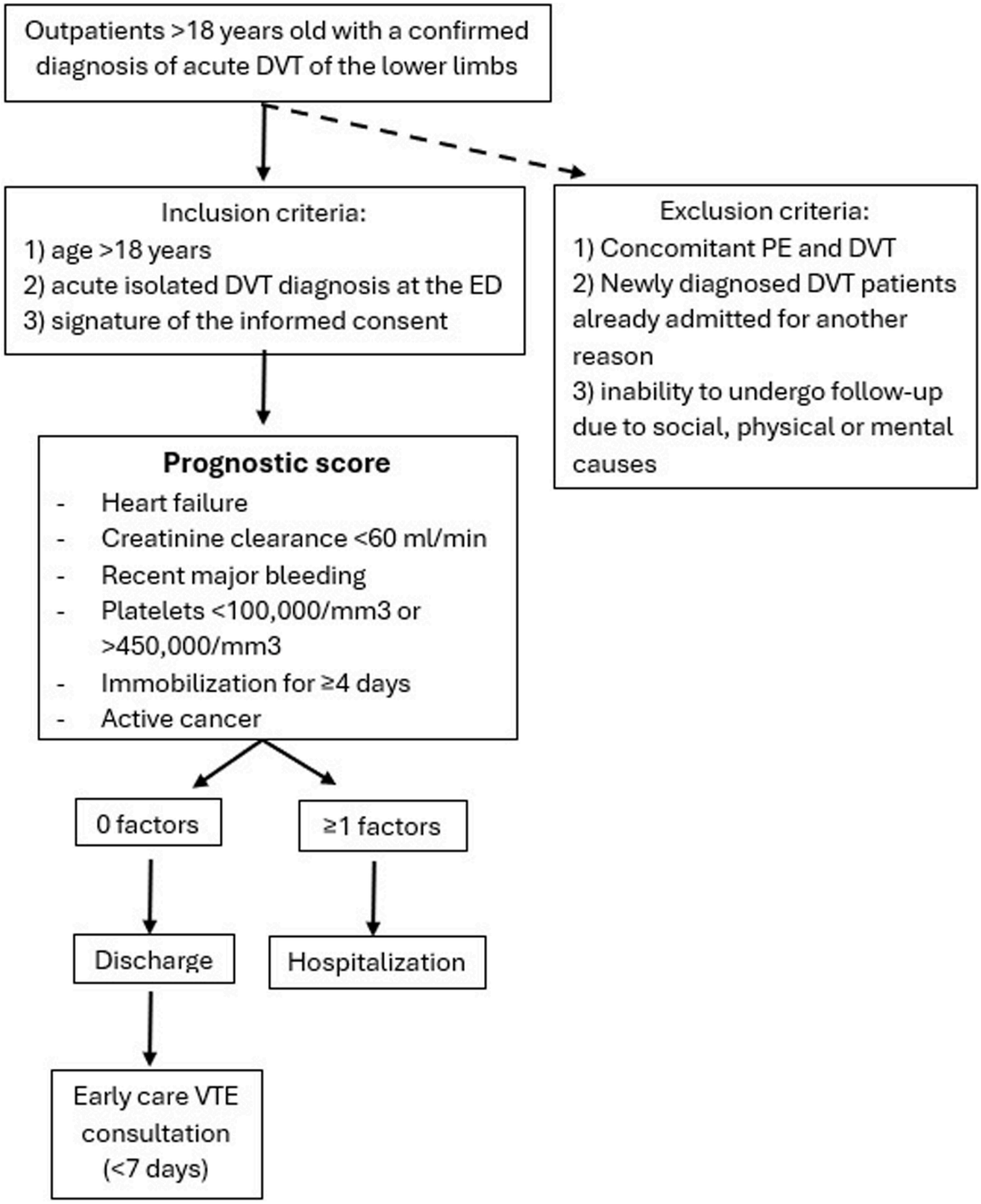

Fig. 1. Algorithm for the management of outpatients with acute deep venous thrombosis in the lower limbs.

The current study undertakes the external validation of the Trujillo-Santos score using a prospective cohort of acute DVT patients diagnosed at the ED of a tertiary hospital over an 8-year period. Additionally, it assesses its clinical safety.

2. Method

2.1. Type of study

This study adopts a single-center prospective observational approach, including consecutive outpatients aged >18 years with a confirmed diagnosis of acute DVT of the lower limbs.

2.2. Patients and setting

Between July 15, 2015, and July 15, 2023 (an 8-year period), consecutive outpatients diagnosed with proximal or distal DVT of lower limbs through imaging tests (lower limb compression ultrasound or contrast-enhanced computed tomography) at the ED of a Spanish tertiary hospital were enrolled. All patients underwent evaluation based on the Trujillo-Santos score at the ED [15]. According to the score, patients scoring 0 were candidates for outpatient treatment, whereas those with a score of 1 or more were candidates for hospitalization. The final decision regarding discharge from the ED was made by the attending physician after considering the score assessment (Fig. 1). A patient was considered 'discharged' if they remained in the ED for <24 h. Patients discharged from the ED were subsequently followed in the early care VTE consultation.

The inclusion criteria comprised: 1) age >18 years; 2) diagnosis of acute isolated lower limbs DVT at the ED; 3) provision of informed consent. Exclusion criteria included: 1) Concomitant PE and DVT; 2) Newly diagnosed DVT patients already admitted for another reason; 3) inability to undergo follow-up due to social, physical, or mental causes.

The early care consultation program commenced on July 15, 2015, offering outpatient care within <7 days to patients diagnosed with acute DVT of the lower limbs in the ED and not meeting any of the exclusion criteria recommended by Trujillo-Santos et al. [15].

The program encompassed both ED and the early care consultation management. ED management included: 1) patient education; 2) measures to facilitate early outpatient follow-up (e.g., scheduling appointments prior to ED discharge); and 3) assessment of medication accessibility. The early care consultation entailed: 1) patient education; 2) assessment of medication accessibility; 3) clinical follow-up; 4) supplementary tests; and 5) treatment decisions adhering to recommendations from clinical guidelines [7,8].

2.3. Variables

Baseline patient data encompassed epidemiological information, characteristics of VTE presentation, and results of additional tests. VTE episodes were categorized as provoked or unprovoked based on the guidelines set forth by the International Society on Thrombosis and Haemostasis [16].

2.4. Study outcomes

The primary outcome of the study was the incidence of a composite outcome, which included a newly confirmed diagnosis of PE, major bleeding, or all-cause death at 7 days. Secondary outcomes comprised the incidence of the composite outcome at 30 days and the proportion of patients meeting zero criteria for safe discharge at 7 and 30 days. Newly diagnosed PE was defined as a filling defect in pulmonary artery CT or ventilation/perfusion mismatch in lung scintigraphy in patients who exhibited respiratory symptoms during follow-up.

Major bleeding was defined as acute clinically overt bleeding associated with one or more of the following: a decrease in the hemoglobin level of at least 2 g/dl, transfusion of 2 or more units of red cells, bleeding occurring at a critical site (intracranial, intraspinal, intraocular, pericardial, intraarticular, intramuscular with compartment syndrome, or retroperitoneal), bleeding necessitating surgical intervention, or fatal bleeding, all occurring during the follow-up period, in accordance with criteria employed in the RIETE registry [17].

Data on DVT diagnosis and study outcomes were collected by at least two experts from the VTE unit who independently reviewed the imaging studies and medical records, in addition to the assessments made by the ED physicians. We implemented a standardized data collection process to ensure consistency and accuracy.

2.5. Follow-up

Following the date of inclusion, patients underwent clinical follow-up in the inpatient VTE Unit or outpatient VTE clinic for a minimum duration of 30 days, during which clinical outcomes were recorded. The initial outpatient consultation for discharged patients occurred within 7 days, followed by a subsequent visit at 30 days, both occurring in the early care consultation setting.

2.6. Ethics and risks

This study adhered to the international ethical recommendations for conducting research involving humans as outlined in the latest revision of the Declaration of Helsinki, as well as those established in the Good Clinical Practice Guidelines and current legislation. Approval for the study was obtained from the Institutional Ethics Committee (order SAS/3470/2009, following the previous act 01/204, on April 27, 2015). Participants were assured of the confidentiality and privacy of all collected information. Prior to inclusion in the study, patients provided signed informed consent.

2.7. Statistical analysis

Qualitative variables were presented using frequency distribution and percentages, while normally distributed quantitative variables were expressed as mean and standard deviation (SD), and non-normally distributed variables were presented as median and 25th (P25) and 75th (P75) percentiles. The association between qualitative variables was assessed using the chi-square test and Fisher's exact test, whereas numeric variables were evaluated using the Student's *t*-test or Mann-Whitney U test. Spearman's correlation coefficient served as a measure of correlation between quantitative variables.

We determined the proportion of patients with no criteria, thus considered at low risk, and those with one or more criteria, hence deemed at high risk. Additionally, patients were stratified based on the number of positive items, and the proportion of patients with the composite outcome in each group was calculated. For all patients discharged according to the prognostic score, we recorded the number of patients who experienced the composite outcome within 7 and 30 days of follow-up.

For the analysis of the primary outcome, assessing the safety of the score, we employed a per-protocol approach. Regarding the analysis of the secondary outcome, evaluating the efficiency of the algorithm, both an intention-to-treat approach and a per-protocol approach were utilized. The distinction between the two approaches lay in the manner in which we reported the proportion of patients who were admitted but not indicated by the score. Cases in which the composite outcome was diagnosed in patients meeting 0 factors were considered to be a failure of the score strategy. Primary and secondary outcomes are reported as percentages with corresponding exact 95 % confidence intervals.

Statistical data was performed using SPSS software (version 20; SPSS Inc., Chicago, IL) and Epidat 3.1 (Xunta de Galicia, OPS, Epidat 3.1, Coruña, 2006, Washington, DC). A P value <0.05 was considered statistically significant.

3. Results

A total of 1680 consecutive outpatients with acute DVT diagnosis were initially screened; 645 patients were excluded for various reasons (Fig. 2). The baseline characteristics of the 1035 patients who participated in the study are summarized in Tables 1 and 2. Among these participants, 564 (54.5 %) were male, with a median age of 66 years, and 569 (55 %) were categorized as having an unprovoked DVT episode. Of the 1035 patients, 485 (46.9 %) did not met any criteria, while 550 (53.1 %) met at least one criterion. The composite outcome was observed in 9 patients within the first 7 days (Fig. 2). No patients were lost to follow-up during the first 30 days.

Of the patients who met 0 criteria, 413 (85,1 %) patients were discharged and 72 (14,9 %) were admitted. The total number of patients who experienced the composite outcome and met 0 criteria was 1 (0.2 %; 95 % CI, 0.005 to 1.143 %) at 7 days and 2 (0.4 %; 95 % CI, 0.050 to 1.482 %) at 30 days. Among the 413 patients (39.9 %) who did not meet any criteria and were discharged, none experienced the composite outcome during the 7-day or 30-day follow-up (0 %; 95 % CI, 0.0 to 0.9 %) (Table 3). Of the 72 patients who were inappropriately admitted (as they did not meet any criteria), 1 patient (1.4 %) experienced major bleeding at 7 days, and 1 patient (1.4 %) died at 30 days.

Of the patients who met ≥1 criteria, 206 (37.5 %) were admitted and 344 (62.5 %) patients were discharged. The total number of patients who had the composite outcome and met at least 1 criterion was 8 (1.4 %; 95 % CI, 0.363 to 2.546 %) at 7 days and 23 (4.1 %; 95 % CI, 2.418 to 5.946 %) at 30 days. Among the 344 patients who met ≥1 criteria and were discharged, 263 patients had 1 criterion, 65 patients had 2 criteria, and 16 patients had ≥3 criteria. Within this subgroup, the criteria were distributed as follows: immobility ≥4 days was present in 158 (45.9 %) patients, creatinine clearance levels <60 mL/min in 124 (36.0 %) patients, active cancer in 117 (34.0 %) patients, altered platelet count in 20 (5.8 %) patients, chronic heart failure in 19 (5.5 %) patients, and recent major bleeding in 4 (1.1 %) patients. Among these, the composite outcome at 7 and 30 days occurred in 2 (0.6 %) and 5 (1.4 %) patients, respectively. The distribution of the risk factors amongst the 344 patients who were discharged and had the composite outcome are summarized on **Supplementary Table 1.**

Among the patients who suffered the composite outcome within the first 7 days, 1 patient did not meet any criteria (0.2 % of the 485 patients who did not meet any criteria), while 8 patients met at least one criterion (1.4 % of the 550 patients who met at least one criterion). PE was diagnosed in 2 patients during the first 7 days, all of whom met at least one criterion (0.3 % of the 550 patients who met at least one criterion). Major bleeding occurred in 5 patients during the first 7 days. Of these 5 patients, 1 did not meet any criteria (0.2 % of the 485 patients who did not meet any criteria), and 4 patients met at least one criterion (0.7 % of the 550 patients who met at least one criterion). Death occurred in 2 patients within the first 7 days, both of whom met at least one criterion (0.3 % of the 550 patients who met at least one criterion). The Table 3 reveals the composite outcome within the first 30 days.

Utilizing the intention-to-treat approach, 757 of the 1035 patients were not admitted (73.1 %; 95 % CI, 70.392 to 75.889 %), whereas the per-protocol approach identified 485 of the 1035 patients (46.9 %; 95 % CI, 43.7 to 49.9 %) as not requiring admission.

The C-statistics of the score were 0.68 (95 % CI, 0.57–0.79) and 0.69 (95 % CI, 0.64–0.76), and the negative predictive values (NPV) were 99.8 % (95 % CI, 98.9 %−100 %) and 99.6 % (95 % CI, 98.5 %−100 %) for the 7-day and 30-day follow-up periods, respectively. The prognostic value of the score for the composite outcome is detailed in Table 4.

4. Discussion

The present study shows that the application of the Trujillo-Santos score is safe and effective in identifying patients diagnosed with acute DVT at low risk of early complications. Its application in conjunction with the establishment of an early care consultation for these patients is a safe strategy and may result in a reduction in the number of hospital admissions. Admission was safely avoided in 39.9 % of the patients (413/1035), thus averting unnecessary costs, and it could have been avoided in 46.9 % of the patients (485/1035) if the score had been followed strictly.

Trujillo-Santos et al. [15] introduced a score in 2015 based on a RIETE cohort of 15,280 outpatients with DVT. This score incorporated six laboratory and clinical variables that independently predicted the risk for the composite outcome (PE, major bleeding, or death). Patients meeting zero criteria were considered at low risk of complications within the first 7 days. Among 11,430 patients (75 %) considered to be at low risk, 0.13 % suffered PE, 0.19 % bled, and 0.07 % died. In the derivation study, the C-statistic was 0.76 (95 % CI 0.72–0.79) for the high versus low-risk score and 0.61 (95 % CI 0.57–0.65) for the discharge versus admission, indicating prognostic improvement using the score compared with the clinical judgement. In our validation study, the C-statistic for the score was a bit lower (0.680) than result from the derivation study (0.76). Athough the NPV of the score should be highlighted as one of its most important characteristics -potentially even more than the C-statistic and accuracy, as it pertains to reliably identifying patients who will not experience complications within the first 7 days- this value is influenced by the prevalence of complications. In the original study by Trujillo-Santos et al., the prevalence was 1.13 % (173 composite outcomes out of 15,280 patients) whereas in the present study it is 0.87 % (9 composite outcomes out of 1035 patients). Therefore, the negative likelihood ratio (LR) is a crucial characteristic to consider in the score. The negative LR was 0.33 in the original study by Trujillo-Santos and 0.24 in our study.

The score was not followed in 62.5 % (344/550) of patients with ≥1 criterion, who were discharged, and this group of patients demonstrated similar safety to patients who had 0 criteria. This suggests that the score could be improved in order to select a larger group of patients with DVT who could still benefit from home treatment. Among these patients, 45.1 % had immobility ≥4 days, 36.0 % had creatinine clearance levels <60 mL/min and 34.0 % had active cancer. This suggests that certain patients meeting only one of these criteria might still be safely discharged. However, this finding should be validated in further studies. Additionally, the early care consultation program provides rapid clinical follow-up for these patients, which likely increased the confidence of ED physicians in discharging patients with DVT who met specific criteria.

A meta-analysis of 21 real-world studies treating DVT patients on an outpatient basis revealed that despite the development of the Trujillo-Santos score, <50 % of patients were managed as outpatients in 11 out 15 evaluable studies, with all studies including periods preceding its publication. Younger age persistently emerged as the only characteristic associated with outpatient treatment in about 70 % of studies [18]. Among these studies, 8 described programs to facilitate outpatient treatment, with only 4 reporting criteria for identifying patients ineligible for outpatient care. Consistently reported factors for ineligibility included elevated bleeding risk and comorbidities like renal or liver disease, along with unreliable follow-up, difficulty obtaining medication, extensive or recurrent DVT, and pregnancy [18].

The score of the present study relied mostly on three criteria: immobility ≥4 days (23.1 %), kidney failure (21.1 %) and active cancer (18.1 %). However, it lacks inclusion of other pertinent criteria such as the extent of thrombosis (3.7 % had iliac vein thrombosis), intravenous pain medication for >24 h, medical or social reasons for hospital treatment, and pregnancy (1.2 % patients were pregnant), as seen in the Hestia score for safe discharge in acute PE patients [19]. We therefore recommend complementing the score with clinical judgement.

What should be considered a safe threshold for deciding against admission in patients with DVT? Prognostic scores for acute PE typically consider a risk of <1 % for mortality or severe morbidity at 30 days as low risk, recommending outpatient management [8,20]. In our study, the 30-day incidence of composite outcome was low, with only one

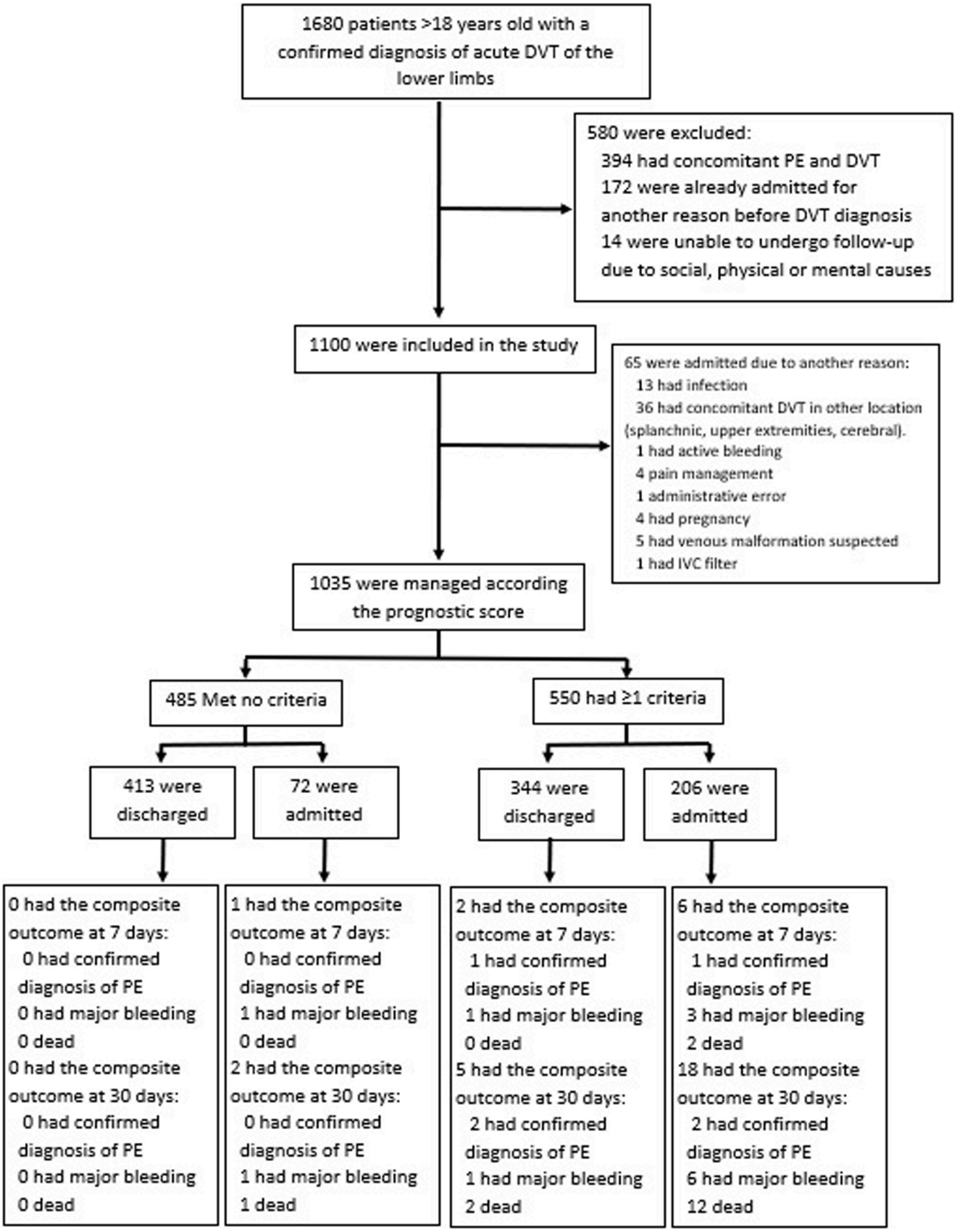

Fig. 2. Enrollment of patients and follow-up. DVT: Deep venous thrombosis; IVC: inferior vena cava.

Table 1
Demographic, baseline characteristics of outpatients diagnosed with acute deep venous thrombosis.

Variable	Patients ($N = 1035$)
Clinical characteristic	
Median age (IQR), year	(66, 52–79)
Sex male, n (%)	564 (54.5 %)
Body mass index, median (IQR), Kg/m2	26.8 (24.3–30.1)
Underlying conditions	
Hypertension, n (%)	478 (46.2 %)
Diabetes, n (%)	138 (13.3 %)
Chronic heart failure, n (%)	44 (4.2 %)
Coronary artery disease, n (%)	41 (4.9 %)
Stroke, n (%)	48 (4.6 %)
Recent major bleeding, n (%)	11 (1.1 %)
Anemia, n (%)*	184 (17.7 %)
Platelet count:	
<100,000, n (%)	28 (2.7 %)
>450,000, n (%)	13 (1.3 %)
Creatinine clearance <60 mL/min	218 (21.1 %)
Risk factors for VTE	
Active cancer, n (%)	187 (18.1 %)
Immobility ≥4 days	239 (23.1 %)
Postoperative	86 (8.3 %)
None of the above	569 (54.9 %)
Prior VTE	127 (12.2 %)
Pregnancy	7 (0.7 %)
DVT presentation	
Proximal DVT	773 (74.7 %)
Iliac DVT	39 (3.7 %)
Bilateral DVT	12 (1.2 %)
Score factors, n (%)	
Immobility ≥4 days, n (%)	239 (23.1 %)
Creatinine clearance levels <60 mL/min, n (%)	218 (21.1 %)
Active cancer, n (%)	187 (18.1 %)
Chronic heart failure, n (%)	44 (4.2 %)
Altered platelet count, n (%)	41 (4 %)
Recent major bleeding, n (%)	11 (1.1 %)
0 criteria	485 (46.8 %)
1 criterion	400 (38.6 %)
2 criterion	113 (10.9 %)
3 or more criterion	37 (3.6 %)
Initial therapy	
Low-molecular-weight heparin, n (%)	893 (86.2 %)
Unfractionated heparin, n (%)	11 (1.1 %)
Fondaparinux, n (%)	0
Rivaroxaban, n (%)	50 (4.8 %)
Apixaban, n (%)	81 (7.8 %)
No anticoagulation, n (%)	0
Vena cava filter, n (%)	16 (1.5 %)

* Anemia: Hemoglobin < 13 g/dl in men and <12 g/dL in women;
IQR: interquartile range; VTE: venous thromboembolism.

Table 2
Outcomes of outpatients diagnosed with acute DVT.

7-day outcome	
Composite outcome	9 (0.9 %)
Symptomatic PE	2 (0.2 %)
Major bleeding	5 (0.5 %)
Overall death	2 (0.2 %)
Fatal PE	0
Fatal bleeding	0
30-day outcome	
Composite outcome	25 (2.4 %)
Symptomatic PE	4 (0.4 %)
Major bleeding	8 (0.8 %)
Overall death	15 (1.4 %)
Fatal PE	0
Fatal bleeding	2 (0.2 %)

PE: pulmonary embolism.

Table 3
7-day and 30-day outcomes.

Variable	All patients ($N = 1035$)	0 criteria ($N = 485$)	≥1 criteria ($N = 550$)
7-day follow-up			
Diagnosis of PE			
n/N	2/1035	0/485	2/550
% (95 % CI)	0.19 % (0.02–0.69 %)	0 % (0.00–0.76 %)	0.3 % (0.04–1.31 %)
Major bleeding			
n/N	5/1035	1/485	4/550
% (95 % CI)	0.48 % (0.16–1.12 %)	0.2 % (0.00–1.14 %)	0.7 % (0.19–1.85 %)
Death			
n/N	2/1035	0/485	2/550
% (95 % CI)	0.19 % (0.02–0.69 %)	0 % (0.00–0.76 %)	0.3 % (0.04–1.31 %)
Composite			
outcome	9/1035	1/485	8/550
n/N	0.87 % (0.26–1.48 %)	0.2 % (0.00–1.14 %)	1.4 % (0.36–2.55 %)
% (95 % CI)			
30-day follow-up			
Diagnosis of PE			
n/N	4/1035	0/485	4/550
% (95 % CI)	0.39 % (0.11–0.99 %)	0 % (0.00–0.76 %)	0.7 % (0.19–1.85 %)
Major bleeding			
n/N	8/1035	1/485	7/550
% (95 % CI)	0.77 % (0.19–1.35 %)	0.2 % (0.00–1.14 %)	1.2 % (0.24–2.30 %)
Death			
n/N	15/1035	1/485	14/550
% (95 % CI)	1.45 % (0.67–2.23 %)	0.2 % (0.00–1.14 %)	2.5 % (1.14–3.95 %)
Composite			
outcome	25/1035	2/485	23/550
n/N	2.42 % (1.43–3.39 %)	0.4 % (0.05–1.48 %)	4.1 % (2.42–5.95 %)
% (95 % CI)			

CI: confidence Interval; PE: pulmonary embolism.

patient (0.2 %) experiencing major bleeding withing the first 7 days and one patient (0.2 %) dying during the first 30 days. Despite the low rate of major bleeding, one in every four patients who experienced major bleeding died within the first 30 days (Table 2). This underscores its clinical relevance. Our study demonstrates reassuring external validity of the score. The positive results observed, including the very low number of early complications and algorithm's ease of use, strongly support the relevance and generalizability of this approach in reducing the proportion of DVT requiring admission, as recommended by current clinical guidelines [6].

Strengths of our study include its prospective design, large sample size, complete follow-up and the objective nature of the criteria, which facilitates evaluation. However, limitations include its single-center nature, nonrandomized design, and application of the score only to ED patients, excluding those already hospitalized. Besides, the adjudication of DVT diagnosis and study outcomes was not performed in a blinded manner. The evaluations were conducted by experts who had access to the clinical data and imaging studies, which could potentially introduce bias. Despite these limitations, the very low observed incidence of failure at 30 days, complete follow-up, and use of a standard design for evaluating strongly support our chosen approach. The high number of patients discharged against the criteria of the score reflects the significant challenges in managing DVT in patients in the ED, which is largely fueled by concerns of both the physician and the patient regarding the short-term complications.

Table 4
Prognostic value of the score and the decision to treat at home for the composite outcome.

	Non-Low Risk vs low Risk	In-hospital Therapy (vs Home Therapy)
Composite Outcome at 7 days		
Sensitivity	88.9 % (51.8 %–99.7 %)	77.8 % (40.0 %–97.2 %)
Specificity	47.2 % (44.1 %–50.3 %)	73.6 % (70.8 %–76.3 %)
Positive predictive value	1.4 % (0.6 %–2.8 %)	2.5 % (1.0 %–5.1 %)
Negative predictive value	99.8 % (98.9 %–100 %)	99.7 % (99 %–100 %)
Positive likelihood ratio	1.68 (1.33–2.14)	2.94 (2.05–4.24)
Negative likelihood ratio	0.236 (0.03–1.50)	0.30 (0.09–1.03)
Accuracy	47.5 (46.8–48.3)	73.6 (72.5–74.2)
C-statistics	0.68 (0.57–0.79)	0.76 (0.61–0.90)
Composite Outcome at 30 days		
Sensitivity	92.0 % (74.0 %–99.0 %)	80.0 % (59.3 %–93.2 %)
Specificity	47.8 % (44.7 %–51.0 %)	74.5 % (71.6 %–77.1 %)
Positive predictive value	4.2 % (2.7 %–6.2 %)	7.2 % (4.4 %–10.9 %)
Negative predictive value	99.6 % (98.5 %–100 %)	99.3 % (98.5 %–99.8 %)
Positive likelihood ratio	1.76 (1.55–2.01)	3.13 (2.51–3.91)
Negative likelihood ratio	0.17 (0.04–0.63)	0.27 (0.12–0.59)
Accuracy	48.8 (47.9–49.7)	74.5 (73.6–75.3)
C-statistics	0.69 (0.64–0.76)	0.77 (0.69–0.85)

Data are shown as value and 95 % confidence intervals.

5. Conclusions

The results of the external validation of the Trujillo-Santos score show that it is safe and effective in identifying acute DVT patients at low risk of early complications. Its application in the ED, coupled with the establishment of an early care consultation for these patients, may lead to a reduction in the number of hospital admissions. Still, a considerable proportion of patients with acute DVT may benefit from outpatient treatment despite having some risk criteria, highlighting the potential for optimizing ambulatory care pathways.

Author contribution

Galeano-Valle F: Visualization, Writing – original draft, Data recompilation, Investigation, Methodology, Writing – review & editing. **Alonso-Beato R:** Statistical analysis, Methodology, Writing – review & editing. **Moragón-Ledesma S:** Investigation, Writing – review & editing. **Pire-García T:** Data recompilation, Investigation. **Huergo-Fernández O:** Data recompilation, Investigation. **Ordieres-García L:** Investigation, Writing – review & editing. **Oblitas CM:** Investigation, Writing – review & editing. **Álvarez-Sala Walther LA:** Writing – review & editing. **Demelo-Rodríguez P:** Visualization, Writing – review & editing, Data recompilation, Investigation, Methodology, Writing – review & editing.

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Declaration of competing interest

The authors declare no conflicts of interest.

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at doi:10.1016/j.ejim.2024.10.007.

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