A simple risk score discriminated between patients at low or high risk for adverse events during therapy for acute DVT

Trujillo-Santos J, Herrera S, Page MA, et al. **Predicting adverse outcome in outpatients with acute deep vein thrombosis. Findings from the RIETE Registry.** J Vasc Surg. 2006;44:789-93.

Clinical impact ratings: Hematol/Thrombo ★★★★★★☆

QUESTION

In patients with acute deep venous thrombosis (DVT) in the lower limbs, does a simple risk score discriminate between patients at low or high risk for early adverse events during initial therapy?

METHODS

Design: 2 cohorts, 1 for derivation and 1 for validation from the Registro Informatizado de la Enfermedad TromboEmbólica (RIETE) registry.

Setting: 103 hospitals in Spain, France, Italy, and Argentina.

Patients: 4405 outpatients (62% > 65 y, 53% men) (2947 for derivation, 1458 for validation) with symptomatic, acute DVT in the lower limbs confirmed by objective tests (compression ultrasonography, contrast venography, impedance plethysmography, or computed tomography [CT]) were followed for 15 days after initiating therapy (e.g., low-molecular-weight heparin, unfractionated heparin, and antivitamin K). Patients with objectively confirmed pulmonary embolism (PE) were excluded from the analysis.

Description of prediction guide: The risk score (range 0 to 14) categorized patients into low- (score ≤ 2) or high-risk (score ≥ 3) groups. Multivariate analysis of risk factors found 6 independent clinical variables that increased risk for adverse events. The risk score was a summation of 6 clinical variables: body weight < 70 kg = 1, cancer = 4, bilateral DVT = 2, immobilization ≥ 4 days = 2, renal insufficiency (creatinine clearance < 30 mL/min = 4; 30 to 60 mL/min = 3), and chronic heart failure = 1.

Outcomes: A composite endpoint of death, recurrent DVT, symptomatic PE, or major bleeding by 15 days.

MAIN RESULTS

138 adverse events developed in 124 (2.8%) patients: 1.5% died, 0.4% had recurrent DVT, 0.3% had symptomatic PE, and 0.8% had major bleeding. The derivation and validation cohorts had similar predictive characteristics within low- and high-risk groups (sensitivity 65.2 vs 59.4; specificity 77.7 vs 78.1) (Table). The area under the receiver-operating characteristic curve was 0.81 (95% CI 0.76 to 0.86) for the derivation cohort and 0.79 (CI 0.70 to 0.88) for the validation cohort.

CONCLUSION

In patients with acute deep venous thrombosis in the lower limbs, a simple risk score provided some discrimination between patients at low or high risk for adverse events during the first 15 days.

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Prevalence of observed and predicted adverse events (AEs) and likelihood ratios (LRs) using a simple risk score in patients with acute deep venous thrombosis*

Risk group (score)	Derivation cohort			Validation cohort		
	Observed AEs	Predicted AEs	LR	Observed AEs	Predicted AEs	LR
Low (≤ 2)	25%	1.2%	0.37	31%	1.0%	0.46
High (≥ 3)	75%	6.8%	2.27	69%	4.7%	2.17

*LR defined in Glossary and calculated from data in article. Adverse events were the composite endpoint of death, recurrent deep venous thrombosis, symptomatic pulmonary embolism, or major bleeding 15 days after initial therapy.

COMMENTARY

The RIETE registry is an ongoing observational study of the epidemiology, management, and outcomes of patients with acute symptomatic DVT, with a large patient sample and rigorous data collection. Trujillo-Santos and colleagues examined this registry to derive and validate a simple clinical prediction guide (CPG) to predict the risk for adverse events during immediate management. The CPG identified a low-risk group in both the derivation and validation cohorts. The authors concluded that the risk score could identify patients at low risk for adverse events, who would therefore be eligible for outpatient treatment. This is reasonable, given that the safety and efficacy of outpatient treatment of DVT has been shown (1, 2).

Several factors argue against concluding that all patients who are labeled as high risk according to the CPG should be hospitalized. First, the study was not designed to address whether in-hospital management would have prevented adverse events or have led to better outcomes after they developed. Second, validation in a separate population and, ultimately, a management study showing better outcomes when the CPG is applied are needed before the CPG can be widely recommended. Finally, the ideal follow-up period to determine potential risk during outpatient treatment is 5 to 7 days (anticipated duration of low-molecular-weight heparin treatment); the follow-up in RIETE was extended to 15 days because the incidence of adverse events in the first week was too low, indicating that many events occurred when heparin had been discontinued. Overzealous use of the CPG before improved outcomes are shown might cause unnecessary hospitalization for a large number of patients.

A review of 17 studies of outpatient treatment of DVT identified 4 criteria that indicate when home treatment might be inappropriate: massive DVT, symptomatic PE, high risk for bleeding on receiving anticoagulation, and comorbid conditions that require hospitalization (3). Until a CPG shows improvement in patient outcomes, clinicians need to be aware that these factors suggest that hospitalization may be necessary for some patients, that ambulatory treatment is appropriate for most other patients, and that close follow-up is essential for successful outpatient treatment regardless of the level of risk.

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