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Effect of a Diagnostic Strategy Using an Elevated and Age-Adjusted D-Dimer Threshold on Thromboembolic Events in Emergency Department Patients With Suspected Pulmonary Embolism: A Randomized Clinical Trial

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Abstract

Importance: Uncontrolled studies suggest that pulmonary embolism (PE) can be safely ruled out using the YEARS rule, a diagnostic strategy that uses varying D-dimer thresholds.

Objective: To prospectively validate the safety of a strategy that combines the YEARS rule with the pulmonary embolism rule-out criteria (PERC) rule and an age-adjusted D-dimer threshold.

Design, settings, and participants: A cluster-randomized, crossover, noninferiority trial in 18 emergency departments (EDs) in France and Spain. Patients (N = 1414) who had a low clinical risk of PE not excluded by the PERC rule or a subjective clinical intermediate risk of PE were included from October 2019 to June 2020, and followed up until October 2020.

Interventions: Each center was randomized for the sequence of intervention periods. In the intervention period (726 patients), PE was excluded without chest imaging in patients with no YEARS criteria and a D-dimer level less than 1000 ng/mL and in patients with 1 or more YEARS criteria and a D-dimer level less than the age-adjusted threshold (500 ng/mL if age <50 years or age in years × 10 in patients ≥50 years). In the control period (688 patients), PE was excluded without chest imaging if the D-dimer level was less than the age-adjusted threshold.

Main outcomes and measures: The primary end point was venous thromboembolism (VTE) at 3 months. The noninferiority margin was set at 1.35%. There were 8 secondary end points, including chest imaging, ED length of stay, hospital admission, nonindicated anticoagulation treatment, all-cause death, and all-cause readmission at 3 months.

Results: Of the 1414 included patients (mean age, 55 years; 58% female), 1217 (86%) were analyzed in the per-protocol analysis. PE was diagnosed in the ED in 100 patients (7.1%). At 3 months, VTE was diagnosed in 1 patient in the intervention group (0.15% [95% CI, 0.0% to 0.86%]) vs 5 patients in the control group (0.80% [95% CI, 0.26% to 1.86%]) (adjusted difference, -0.64% [1-sided 97.5% CI, -∞ to 0.21%], within the noninferiority margin). Of the 6 analyzed secondary end points, only 2 showed a statistically significant difference in the intervention group compared with the control group: chest

imaging (30.4% vs 40.0%; adjusted difference, -8.7% [95% CI, -13.8% to -3.5%]) and ED median length of stay (6 hours [IQR, 4 to 8 hours] vs 6 hours [IQR, 5 to 9 hours]; adjusted difference, -1.6 hours [95% CI, -2.3 to -0.9]).

Conclusions and relevance: Among ED patients with suspected PE, the use of the YEARS rule combined with the age-adjusted D-dimer threshold in PERC-positive patients, compared with a conventional diagnostic strategy, did not result in an inferior rate of thromboembolic events.

Trial registration: ClinicalTrials.gov Identifier: [NCT04032769](https://clinicaltrials.gov/ct2/show/study/NCT04032769).

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