Treating pulmonary embolism at home?

For select patients, acute PE can be managed safely and effectively without hospitalization.

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PRACTICE CHANGER

Treat low-risk patients with pulmonary embolism (PE) with low-molecular-weight heparin (LMWH) in an outpatient setting.[1]

Aujesky D, Roy PM, Verschuren F, et al. Outpatient versus inpatient treatment for patients with acute pulmonary embolism: an international, open-label, randomised, non-inferiority trial. *Lancet.* 2011; 378:41-48.

STRENGTH OF RECOMMENDATION

B: Based on one good quality randomized controlled trial (RCT).

ILLUSTRATIVE CASE

Three months after undergoing surgical repair of an ankle fracture, a 50-year-old woman presents with acute onset dyspnea at rest and pleuritic chest pain. Her left calf is tender and swollen. The patient has a history of hypertension and smokes about 10 cigarettes per day. Her temperature is 37˚C (99˚F); pulse rate, 98; blood pressure, 135/85 mm Hg; respiratory rate, 25; and pulse oximetry, 92%.

You order a spiral CT, which reveals a contrast filling defect indicative of a PE. Her score on the Pulmonary Embolism Severity Index (PESI) is 50, an indication of low risk. She wants to know if she can be treated at home. What should you tell her?

In the past, intravenous unfractionated heparin, administered in an inpatient setting, was the recommended initial anticoagulation therapy for patients with venous thromboembolism (VTE). LMWH, which can be administered subcutaneously and does not require laboratory monitoring, has made it possible to treat VTE without hospitalization.

Outpatient PE care hindered by lack of evidence

Guidelines from the American College of Physicians, American Academy of Family Physicians, and British Thoracic Society recommend outpatient treatment of deep vein thrombosis with LMWH, which they find to be safe and cost effective for select patients.[2,3] Until recently, the safety and efficacy of outpatient management of PE has been less clear.

The lack of an accurate prediction tool to identify patients who could be treated safely outside of the hospital was one barrier to the development of evidence-based recommendations for outpatient PE treatment. In 2005, the PESI,[4] a validated tool that identifies patients with low risk of death from PE, was developed. Until recently, the absence of an RCT comparing inpatient and outpatient treatment for acute PE was another barrier.

STUDY SUMMARY

Outpatient treatment measures up

The Outpatient Treatment of Pulmonary Embolism (OTPE) study was a multinational, randomized, noninferiority trial comparing outpatient vs inpatient treatment of low-risk patients with acute PE. Participants had to be ≥18 years old, have acute symptomatic and objectively verified PE, and be at low risk of death based on the PESI score.[4] In addition to excluding patients at moderate or high risk, the researchers identified 14 other exclusion

Outpatient care of PE: Tips from an emergency physician
Donald M. Yealy, MD

Outpatient management of PE should be considered only for patients who are able to follow instructions and self-inject low-molecular-weight heparin.

criteria, including hypoxia, chest pain requiring opiates, and high risk for bleeding.

Patients were randomly assigned to the outpatient (n=171) or inpatient (n=168) group. Both groups received subcutaneous LMWH (enoxaparin, 1 mg/kg twice a day) for ≥5 days, followed by oral anticoagulation with a vitamin K antagonist for ≥90 days. Patients in the outpatient group were discharged from the emergency department (ED) within 24 hours of randomization, after being trained by a nurse to self-inject. Therapy after discharge was managed either by the patient's primary care physician or the hospital's anticoagulation staff.

The LMWH was discontinued in patients with an INR ≥2.0 for 2 consecutive days. All patients were followed for 90 days, and contacted by the study team daily for the first week and then at 14, 30, 60, and 90 days. On each occasion, participants were asked about symptoms of recurrent VTE, bleeding, and the use of health care resources.

The primary outcome was the recurrence of symptomatic, objectively confirmed VTE within the study period. Secondary outcomes were major bleeding and all-cause mortality. Outcomes were confirmed by clinicians who were unaware of treatment assignments.

Patients were also asked to rate both their overall satisfaction with their care and their treatment preference 14 days after randomization, using a 5-point Likert questionnaire. Prior to the trial, the investigators decided that outpatient treatment would be considered noninferior to inpatient care if the difference between rates of recurrent VTE did not exceed 4%, a measure used in previous studies comparing treatment regimens for VTE and outpatient vs inpatient treatment of DVT.[5,6]

Little difference in readmission rates, ED or office visits

One in 171 outpatients (0.6%) and none of the inpatients had recurrent VTE. Two outpatients (1.2%)—and no inpatients—developed major bleeding within 14 days, the result of intramuscular hematomas that occurred on Days 3 and 13. There was one additional bleeding event (menometrorrhagia) in the outpatient group on Day 50, but it was believed to be unrelated to the PE treatment. Per-protocol analysis, a more conservative measure used in noninferiority studies, found a difference in major bleeding rates of 3.8%. One person in each group died from non-VTE and nontreatment-related causes.

Almost all participants (99%) completed the satisfaction survey, which indicated that 92% of outpatients and 95% of inpatients were satisfied or very satisfied with their care. Hospital readmission rates, ED visits, and visits to primary care physicians were similar, with no significant differences between the 2 groups. The mean time spent in the hospital was 0.5 days (standard deviation [SD], 1.0) for outpatients and 3.9 days (SD, 3.1) for inpatients. Fourteen percent of outpatients and 6% of inpatients received home nursing visits for enoxaparin injection. The total number of home visits was higher among outpatients (348 vs 105). Because both groups had extreme outliers, however, this difference was not statistically significant.

WHAT'S NEW

It's safe to keep low-risk patients at home

This is the first RCT comparing the safety and effectiveness of outpatient and inpatient treatment of acute, symptomatic PE. Results were statistically comparable, and patients were satisfied being treated at home. Outpatient treatment was less expensive because of the shorter length of stay (0.5 vs 3.9 days) and was associated with the same rates of hospital readmission, ED visits, and visits to primary care physicians. There were more home nursing visits in the outpatient treatment group. But even if you assume a cost of $200 per home visit, the additional cost would be about $282 per individual in the outpatient group—significantly less than the cost of the additional 3.4 days in the hospital for each individual in the inpatient group.

The study also confirmed that the PESI accurately identifies low-risk patients with PE who can be treated in an outpatient setting. Thirty percent of patients who were screened for the OTPE trial met the low-risk eligibility requirement.

CONTINUED

CAVEATS

Use of risk assessment tool is essential

The average age of patients in this study was 47 years in the outpatient group and 49 years in the inpatient group. In addition, only 1% to 3% of the patients were diagnosed with cancer. Older patients who have both cancer and PE would be unlikely to qualify for outpatient care.

Physicians applying this practice changer should use the PESI to ensure that outpatient treatment for PE is used only for individuals at low risk.

CHALLENGES TO IMPLEMENTATION

ED coordination, training, and home care won't be easy

This practice changer may be difficult for family physicians, who might not be included in emergency physicians' decisions regarding the appropriate treatment for acute PE. In this study, primary care physicians were notified of the randomized treatment plan for their patients, and 17 potential participants were excluded from the trial because of their doctors' opposition.

Outpatient management should be considered only if arrangements for adequate home nursing care can be made, if needed—and only for patients who are able to follow instructions and self-inject LMWH. Newer anticoagulation medications that are either injected once a day or taken orally might decrease the need for home nursing visits. JFP

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