

Appendix

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Pulmonary Embolism Severity Index (PESI)

The Pulmonary Embolism Severity Index (PESI) is a well externally validated risk stratification tool to determine the 30-day mortality risk of patients with newly diagnosed pulmonary embolism. It consists of a list of 11 patient clinical characteristics (1). A score is assigned by summing the patient's age in years and the points for each characteristic present. The points assignments correspond with the following risk classes: ≤ 65 : Class I, Very Low Risk; 66-85: Class II, Low Risk; 86-105: Class III, Intermediate Risk; 106-125: Class IV, High Risk; > 125 : Class V, Very High Risk. The patient characteristics with the assigned points are the following: Age [points equal to the age in years]; Male sex [+10 points]; Cancer [+30 points]; Heart failure [+10 points]; Chronic lung disease [+10 points]; Pulse ≥ 110 /min [+20 points]; Systolic blood pressure < 100 mmHg [+30 points]; Respiratory rate ≥ 30 /min [+20 points]; Temperature $< 36^{\circ}\text{C}$ [+20 points]; Altered mental status [+60 points]; Arterial oxygen saturation $< 90\%$ [+20 points].

Qanadli Score

The degree of pulmonary arterial obstruction observed with the multidetector-row computed tomography scanning that diagnosed the initial PE event was assessed through the calculation of a quantitative CT index, according to the method validated by Qanadli (2). The arterial tree of each lung was divided into 10 segmental arteries (three to the upper lobes, two to the middle lobe and the lingula, and five to the lower lobes). The presence of embolus in a segmental artery was given 1 point, and emboli in the most proximal arterial level were given a value equal to the number of segmental arteries arising distally. A weighting factor was assigned to each value, depending on the degree of vascular obstruction (i.e. 0 = no thrombus; 1 = partially occlusive thrombus; 2 = total occlusion). Isolated subsegmental embolus was considered as a partially occluded segmental artery and was assigned a value of 1. The maximal CT obstruction index was 40 per patient. The percentage of vascular obstruction was calculated by dividing the patient score by the maximal total score and by multiplying the result by 100. Therefore, the CT obstruction index can be expressed as: $\Sigma(n \times d) / 40 \times 100$, where n is the value of the proximal thrombus in the pulmonary arterial tree equal to the number of segmental branches arising distally (minimum, 1; maximum, 20), and d is the degree of obstruction (minimum, 0; maximum, 2).

Meyer Score

The extension of pulmonary perfusion defects observed with the initial and the 6-month lung scan was assessed through the calculation of the degree of vascular obstruction according to the method validated by Meyer and others (3). Each lobe was assigned a weight based on the regional distribution of pulmonary blood flow in the supine position: right lower lobe 25%, right middle lobe 12%, right upper lobe 18%, left lower lobe 20%, lingula 12%, and left upper lobe 13% (4). Perfusion was then estimated, within each lobe, from the anterior, posterior and oblique views. For each lobe, a semi-quantitative perfusion score from 0 to 1 (0, 0.25, 0.5, 0.75 or 1) was estimated from the film density by comparison with the photodensity of an apparently normally perfused area. Each lobar perfusion score was then calculated by multiplying the weight by the perfusion score. The overall perfusion score was determined by summing the six separate lobar perfusion scores. The percentage of vascular obstruction by perfusion scanning was then calculated as $(1 - \text{Overall perfusion score}) \times 100$.

Sample size calculation

The paucity of available evidence did not allow a precise estimate of the sample size, which was calculated based on 80% power to detect a hazard ratio of 2.5 in subjects with residual pulmonary obstruction, while accepting a two-sided alpha error of 0.05, assuming an incidence, after three years, of VTE recurrence equal to 5% and of CTEPH equal to 2%. Another assumption was a rate of residual pulmonary obstruction equal to 50% of overall enrolled patients. This yielded an initial sample size of 1000 patients. The subsequent enrolment was interrupted by the Steering Committee after the inclusion of 750 patients because of slow recruitment rate.

References

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