Hospitalisation or Outpatient Management of PE Patients – HESTIA vs. Simplified PESI

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Background

- European guidelines recommend the Pulmonary Embolism Severity Index (PESI) score or the simplified PESI score (sPESI) to assess the risk of all-cause mortality.
- Patients with an sPESI score of 0 can be treated at home, providing that proper follow-up and anticoagulant therapy can be provided.
- American guidelines do not require a predefined score, and advise using pragmatic criteria such as those in the Hestia Study.

AIM of the study

- To examine whether a strategy based on the Hestia criteria was at least as safe as a strategy based on the sPESI score to select patients for home treatment.
- To evaluate whether the Hestia method was more efficient compared to the sPESI score – in other words, whether it led to more patients being selected for home treatment.

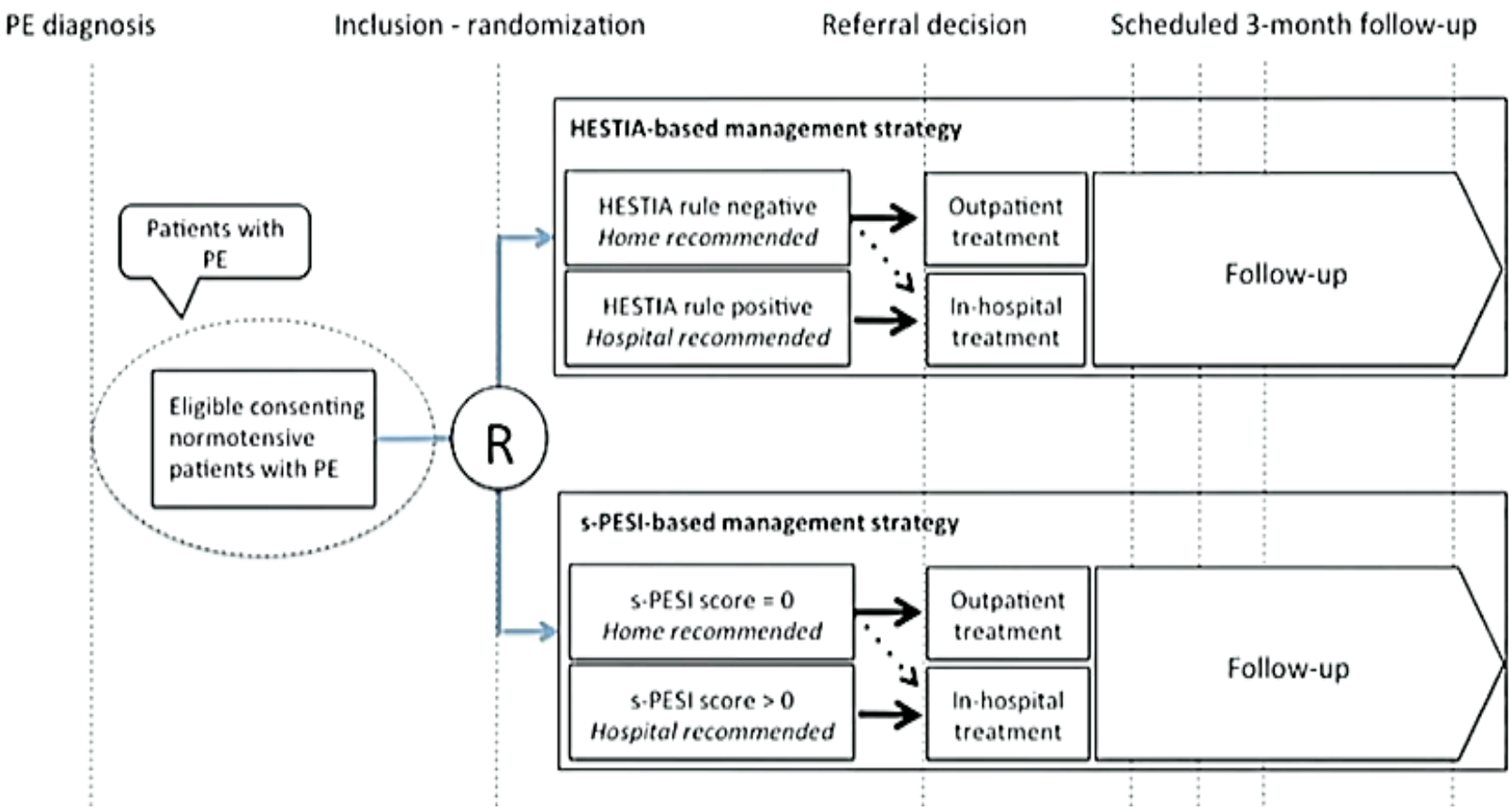
Methods (I)

- Randomised, open-label non-inferiority trial.
- 26 hospitals in France, Belgium, the Netherlands and Switzerland.
- Primary outcome: composite of recurrent VTE, major bleeding and all cause mortality at 30 days.
- Follow up 90 days.

Methods (II)

- 1,974 patients with normal blood pressure presenting to the emergency department with acute pulmonary embolism were included.
- Patients randomized to the sPESI group were eligible for outpatient care if the score was 0; otherwise they were hospitalized.
- Patients randomized to the Hestia group were eligible for outpatient care if all 11 criteria were negative; otherwise they were hospitalized.
- In both groups, the physician in charge could overrule the decision on treatment location for medical or social reasons.

Study design



Results

- The Hestia strategy was non-inferior to the sPESI strategy: the primary outcome occurred in 3.8% of the Hestia group and 3.6% of the sPESI group (p=0.005).
- A greater proportion of patients were eligible for home care using sPESI (48.4%) compared to Hestia (39.4%). However, the doctor in charge of the patient overruled sPESI more often than Hestia. Consequently, a similar proportion of patients were discharged within 24 hours for home treatment: 38.4% in the Hestia group and 36.6% in the sPESI group (p=0.42).
- All patients managed at home had a low rate of complications.

	HESTIA strategy (N=984)	sPESI strategy (N=986)		
Main outcome				
In the per-protocol population	*n° of patients with event/total n° of patients (%)*		Adjusted absolute difference* (90%CI)	
Composite of recurrent VTE, major bleeding and all-cause death at 30 days	34/891 (3.82)	32/896 (3.57)	0.20% (-1.03 to 1.43)	P=0.01
Major Secondary outcomes			Adjusted absolute difference* (95%CI)	
In the intention-to-treat population				
Rate of patients actually treated as outpatients	378/984 (38.4)	361/986 (36.6)	1.78% (-2.40 to 5.96)	P=0.41

	HESTIA strategy (N=984)	sPESI strategy (N=986)	
In the per-protocol population	*n° of patients with event/total n° of patients (%)*		Adjusted absolute difference* (90%CI)
Efficacy of the rule			
Rate of low-risk patients eligible for outpatient care according to the rule	388/984 (39.4)	477/986 (48.4)	-8.91% (-13.3 to -4.56)
Applicability of the rule			
Patients treated as outpatients among eligible patients	343/388 (88.4)	309/477 (64.8)	25.3 % (19.5 to 31.1)

Conclusions

- For outpatient care of normotensive PE patients, the triaging strategy based on the Hestia rule was non inferior to the strategy based on the sPESI score.
- The two strategies do not significantly differ with respect to the proportion of patients managed at home or early discharged.
- In hospitals organized for outpatient management, both triaging strategies enable more than a third of pulmonary embolism patients to be managed at home with a low rate of complications.