Journal Club Eastern Virginia Medical School
Therapy Article

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CITATION:
Outpatient treatment in patients with acute pulmonary embolism: the Hestia Study, J Thromb, 2011; 9(8):1500-1507.

I. **WHAT IS BEING STUDIED?**	
1. Study Objective	Evaluate the efficacy and safety of outpt treatment of low-risk patient's presenting with acute PE who did not meet any 1 of 11 exclusion criteria
2. Study Design	Multicenter prospective cohort study of consecutive patients presenting to 12 hospitals (2 academic and 10 community) in the Netherlands between May 2008 and April 2010
3. Inclusion Criteria	➢ 18 years old ➢ Objectively proven acute PE
4. Exclusion Criteria	➢ Hemodynamically unstable ➢ Needed thrombolysis or embolectomy ➢ Active bleeding/ high risk of bleeding ➢ Supplemental O2 needed for >24 hrs to maintain Pox >90% ➢ Diagnosis during anticoagulant tx ➢ IV pain meds for >24 hrs. ➢ Medical or social reason for tx in the hospital for >24 hours (i.e. infection, malignancy no support system) ➢ Cr clearance <30 mL min ➢ Severe liver impairment ➢ Pregnant ➢ Hx of HIT
5. Interventions Compared	Single armed study evaluating inpt vs outpt tx of PE

6. Outcomes Evaluated	➢ Primary Endpoint: Symptomatic objectively proven recurrent VTE during 3 months of f/u ➢ Secondary Endpoints. Major bleeding and death
II. **Are the results of the study valid**	
1. Was the assignment of patients randomized?	No, it was a single armed study. But it did use consecutive patients. (581 total pts, 243 ineligible). Authors felt RCT would require a very large sample size.
2. Was randomization concealed (blinded)?	Unable to be blinded d/t single armed study, but endpoint ascertainment was performed according to predefined criteria.
3. Were patients analyzed in the groups to which they were randomized?	Singled armed study with intention to treat analysis though they report 100% follow-up.
4. Were patients in the treatment and control groups similar with respect to known prognostic factors?	Tx grp was compared to rates of other studies. There was no control group
III. **Did experimental and control groups retain a similar prognosis after the study started (answer the questions posed below)?**	
1. Were patients aware of group allocation?	Yes
2. Were clinicians aware of group allocation?	Yes
3. Were outcome assessors aware of group allocation?	Yes
4. Was follow-up complete?	3 month follow-up was completed for all patients
IV. What were the results? Answer the questions posed below	
1. How large was the treatment effect? (Difference between treatment and control group).	➢ Recurrence rate of VTE was 2%. Compared to prior studies, this was very similar. (rate 3.0%) ➢ Fatal bleeding occurred in 0.3%.

	Fatal bleeding rates of 0.3-0.6% in hospital when compared to prior studies.
2. What was the estimated treatment effect at a 95% confidence interval? (Precision)	Five patients had recurrent VTE: 2% (CI 0.8-4.3%) Two patients had major bleeding episode 0.7% (CI 0.008- 1.9) Three patients 1.0% (95% CI 0.2-2.9) died during the 3-month f/u,,none from PE.
V. **Will the results help me in caring for my patients? (Applicable?)**	
1. Were the study patients similar to my patient?	Possibly. Study conducted at 12 hospitals in the Netherlands. Differences in socioeconomic status most likely present when compared to my patients. All had access to their national healthcare system during interim. Symptom wise, patients would be similar once exclusion criteria applied.
2. Were all clinically important outcomes considered?	Compared recurrent VTE, major bleeding, death. I think these would be the main deciding factors for me when considering initiating outpt therapy for my patients. No economic analysis or patient preference
3. Are the likely treatment benefits worth the potential harm and costs?	Yes, large financial benefit from reduced hospitalization rate. Improved quality of life for patients who can be treated at home vs staying in the hospital. Needs validation by RCT and in a USA cohort.

Study Limitations:

1. **Endpoint ascertainment could not be blinded. (single armed study design)**
2. **Not all recurrent VTEs were objectively diagnosed w/ imaging. Therefore, VTE recurrence rate might be overestimated.**
3. **Needs a randomized trial to confirm results.**
4. **No validation of their 11 exclusion criteria**

Clinical Bottom Line: Outpatient treatment of PE could be feasible to selected low-risk patients without added risk, but more research is needed to confirm.