Critical Review Form Prognosis

Frizell A, Fogel N, Steenblik J, Carlson M, Bledsoe J, Madsen T.

Prevalence of pulmonary embolism in patients presenting to the emergency department with syncope. Am J Emerg Med. 2018 Feb;36(2):253-256.

Objectives: "to evaluate data from our ED to determine the prevalence of PE in patients presenting with syncope." (p. 253)

Methods: This retrospective observational study was conducted using data that previously collected in a prospective fashion. Adult patients (aged 18 years or older) presenting to the ED at the University of Utah between July 2010 and December 2015 with syncope within the last 24 hours were eligible for inclusion. Prisoners, individuals not capable of giving consent, those who refused consent, and those unable to complete the survey due to additional testing or lack of time were excluded. Patients were only enrolled when a research associate was available, which was from 8 AM to midnight 7 days a week, excluding university holidays and semester breaks. Providers were blinded to study aims and all testing was performed at the discretion of the treating clinicians.

Information was obtained via a standard questionnaire administered by the research associates. They also recorded important ED data (including vital signs, lab results, and imaging results), and the results of testing and patient outcomes for patients admitted to the inpatient service or ED observation unit (EDOU). Telephone follow-up was attempted for all patients at least 30 days after the ED visits to determine additional testing or diagnoses. For those patients who could not be contacted, the medical records were reviewed for additional information.

During the study period, 778 patients with syncope were screened for enrollment, of whom 348 were enrolled. The mean age was 48.4 years and 52% were female. Among enrolled patients, 15.8% reported a previous history of PE or DVT, 54.3% endorsed shortness of breath, 49.1% endorsed chest pain, and 17% reported calf pain or swelling.

Guide		Comments
I.	Are the results valid?	
A.	Was the sample of patients	No. Patients were only recruited during certain
	representative?	daytime hours (8 AM to midnight) and were not
	In other words, how were subjects	recruited on holidays (convenience sample). The
	selected and did they pass through	authors were unable to provide any comparison
	some sort of "filtering" system	between eligible patients seen during off-hours
	which could bias your results based	and those actually enrolled. All patients seen
	on a non-representative sample.	during recruitment hours with syncope within

В.	Also, were objective criteria used to diagnose the patients with the disorder? Were the patients sufficiently homogeneous with respect to prognostic risk? In other words, did all patients share a similar risk from during the study period or was one group expected to begin with a higher morbidity or mortality risk?	the previous 24 hours were eligible for enrollment, and only patients seen in a single, academic emergency department in Utah were included. These results may not be applicable in disparate settings, such as rural EDs (external validity). Yes and no. Although the authors included all patients seen in the ED for syncope, they also provided sufficient outcome information to separate patients discharged from the ED from those who were admitted for further evaluation of syncope. The risk in admitted patients would presumably be higher (as it was in the study by Prandoni et al). There was very little demographic information provided in the article,
		and specific risk factors (cancer, recent surgery, abnormal vital signs) that would affect risk were not detailed.
C.	Was follow-up sufficiently complete? In other words, were the investigators able to follow-up on subjects as planned or were a significant number lost to follow-up?	No. Only 68.4% of patients could be contacted by telephone. Follow-up for the remaining patients occurred by chart review alone. Patients diagnosed with PE at other institutions would not be captured by this method.
D.	Were objective and unbiased outcome criteria used? Investigators should clearly specify and define their target outcomes before the study and whenever possible they should base their criteria on objective measures.	No. While objective diagnostic modalities were used to confirm PE in patients tested in the ED or during the hospitalization, not all patients underwent any testing and not all patients necessarily underwent any clinical risk stratification for PE. More importantly, patients with reportedly were diagnosed with PE in follow-up did not have any verification of the diagnosis.
II.	What are the results?	
A.	How likely are the outcomes over time? For the defined follow-up period, how likely were subjects to have the outcome of interest.	 Out of the cohort of 348 patients, only 2 (0.6%, 95% CI 0.2-2.1%) were diagnosed with a PE in the ED. No admitted patients were diagnosed with PE during their hospital stay. Among patients discharged from the ED (n = 169, none were diagnosed with PE during the ED visit, while one patient was diagnosed with PE during 30-day follow-up, for an overall PE rate of 0.6% (95% CI 0.1 to 3.3%). Among patients admitted from the ED (n = 177), 2 cases of PE were diagnosed during the ED visit and an additional 2 patients (both of whom had a negative CT-PE in the ED) claimed to have been diagnosed with PE after

		 discharge. Neither case was verified in the hospital record. This would result in an overall rate, among admitted patients, of 2.3% (95% CI 0.9-5.7%). The overall rate of PE the entire cohort, including presumed cases diagnosed in follow-up, was 1.4% (95% CI 0.6-3.3%).
В.	How precise are the estimates of likelihood? In other words, what are the confidence intervals for the given outcome likelihoods?	See above.
III.	How can I apply the results to patient care?	
A.	Were the study patients and their management similar to those in my practice?	Likely yes. Despite obvious differences in the racial make-up in Utah compared to St. Louis, these were patients being evaluated in the ED of an academic medical center, and the risk of PE would likely be similar to what is observed in our institution.
В.	Was the follow-up sufficiently long?	Yes. The authors looked not only at diagnosis of PE at the index hospitalization, but also looked at outcomes out to 30 days. Beyond 30 days, it is doubtful that any additional venous thromboemboli would be related to the index syncope event.
C.	Can I use the results in the management of patients in my practice?	Yes (to an extent). The prevalence of PE among all ED patients presenting with syncope was low, and was well below the test threshold for PE of 1.8%. The prevalence of PE among hospitalized patients, including those diagnosed in follow-up, was higher (2.30%), which is above the test threshold, but is still quite low. If patients with obvious clinical signs and symptoms of PE were excluded, it is likely that this number would be below the test threshold.

Limitations:

- 1. This was a retrospective examination of previously collected data, which is subject to several type of bias, including <u>recall bias</u> and misclassification bias.
- 2. This was a single-center study with a rather small sample size.
- 3. Patients were only enrolled when a research associate was available, which was from 8 AM to midnight 7 days a week, excluding university holidays and

semester breaks (<u>convenience sample</u>). There was not way to compare those patients enrolled and those missed during off hours to ensure that these patient populations did not differ significantly.

- 4. Less than half of potentially eligible patients were enrolled, and research associates did not record reasons for failure to complete study enrollment among those not enrolled.
- 5. This study was conducted in Utah, which as a different racial make-up from that seen in our institution (<u>external validity</u>). Of note, only 3.2% of patients were African-American.
- 6. Follow-up was conducted by telephone, only occurred in about two-thirds of patients (attrition bias), and no verification of reported cases of PE was made. Among patients who could not be contacted, follow-up occurred by chart review alone. Patients diagnosed with PE at other institutions would not be captured by this method.

Bottom Line:

This retrospective study looking at the prevalence of PE among ED patients with syncope found a very low rate of PE among all enrolled patients (0.6%; 95% CI 0.1 to 3.3%) with a somewhat higher rate among admitted patients (2.3%; 95% CI 0.9-5.7%). While the prevalence among admitted patients is above the previously derived test threshold, that does not mean routine testing should be performed, as this study potentially included patients with obvious clinical signs of PE. Excluding these patients would likely result in a lower prevalence.