Pulmonary Embolism: Assessment, risk-stratification, and treatment plan for the outpatient management of low-risk patients

Presentation by
Joshua T. Wood, PharmD/PGY-1 Resident
Providence St. Patrick Hospital; Missoula, MT

- Co-Investigators
  - Jayme Hartzell, PharmD, MS, BCPS
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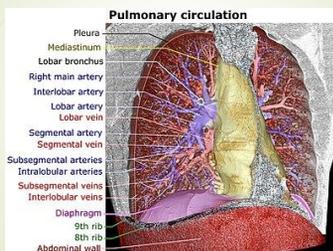- Study sponsorship: None

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Objectives

- 1) Compare and contrast the various validated tools for the identification of patients with pulmonary embolism

- 2) Distinguish between the different risk and mortality algorithms that exist and the merits of using multiple criteria for stratification

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Background

- What is a Pulmonary Embolism
  - Venous thrombosis transported within circulation to pulmonary arterial circulation
  - Blocks arterial lumen
  - Compromises downstream perfusion
  - Resulting in cardiac and respiratory compromise
- Presentation
  - May present as acute, sub-acute, or chronic
- Location
  - Saddle, Lobar, Segmental, Sub-segmental

Background

Pulmonary circulation

Pleura
Mediastinum
Lobar bronchus
Right main artery
Interlobar artery
Lobar artery
Lobar vein
Segmental artery
Segmental vein
Subsegmental arteries
Intralobular arteries
Subsegmental veins
Interlobular veins
Diaphragm
9th rib
8th rib
Abdominal wall

Background

- Pulmonary Embolism (PE)
  - Second leading cause of sudden cardiac death, and third leading cause of cardiovascular death in the US
  - >100,000 deaths annually in the US
  - 5-10% of hospital related deaths
  - 75-269 cases per 100,000 annually worldwide
  - Increased incidence of 700 per 100,000 after the age of 60
  - Increased testing
    - Higher rate of diagnosis
    - Increased morbidity and mortality
      - Renal failure, hemorrhage, and cancer

Background

- Traditionally required hospitalization due to treatment options
- Advent of low-molecular weight heparins (LMWH's) and direct oral anticoagulants (DOAC's) increased feasibility of outpatient therapy
- Outpatient treatment of "low-risk" patients has been shown in studies to be non-inferior to inpatient treatment
  - Confirmed via validation studies with low adverse event rates in the first 3 months following diagnosis
- The American College of Chest Physician Guidelines indicate that risk tools may be utilized to identify patients at "low-risk" for adverse events and early mortality
- These patients may be discharged home for treatment
- Treatment options recommended in the 2016 guidelines include, DOAC's, Vitamin-K antagonists(warfarin), and LMWH

Methods

- Retrospective, single-center, quasi-experimental study
- Pre-intervention data collection (Complete)
- Intervention (Complete)
  - Algorithm implementation and provider education
- Post-intervention data collection (In process)
- Data gathered utilizing electronic health record

Methods

- Inclusion criteria
  - Age ≥ 18 years old
  - Patients diagnosed with a PE and admitted/treated by the Emergency Department, or referred to the Emergency Department for confirmation of suspicion of PE

- Exclusion criteria
  - Patients admitted directly to the hospital from outlying facilities or clinics
 - Patients with previously confirmed or treated PE

Methods

- Primary outcome
  - Number of patients re-admitted within 30 days

- Secondary outcomes
  - Effectiveness of predictive tools in diagnosis of pulmonary embolism
  - Quantity of patients qualifying for outpatient treatment by Hestia Criteria
  - Recurrence rate of PE
  - All-cause mortality at 30 and 90 days
  - Rate of major bleeding events
  - Average length of stay

Intervention

- Assessment algorithm
  - Diagnostic strategy algorithm
  - Pretest probability assessment (Wells Score and PERC)
  - Additional risk stratification (D-Dimer(age-adjusted, imaging studies)
- Risk stratification algorithm
  - Severity and risk assessment (Hestia Criteria)
  - Mortality risk assessment (Clinical Features Correlated for Mortality Risk)
  - Bleeding risk assessment (HAS-BLED Score)
- List of Recommended outpatient treatment options

Intervention
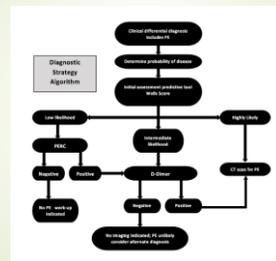
Intervention

Wells Score and Clinical Probability of PE

Criteria	Wells Score
History of PE or DVT	1.5
Heart rate > 100 beats/min	1.5
Recent surgery or immobility	1.5
Hemoptysis	1
Active malignancy	1
Signs of DVT	3
Alternative diagnosis to PE less likely	3
Three-Level Clinical Probability of PE	
Low	0-1
Intermediate	2-6
High	≥ 7
DVT = deep vein thrombosis; PE= pulmonary embolism	

Intervention

Pulmonary Embolism Rule-out Criteria

	Yes	No
Age > 49		
Heart rate ≥ 99 beats/min		
Pulse oximetry < 95% on room air		
Hemoptysis		
Exogenous estrogen supplementation		
History of venous thromboembolism		
Surgery or trauma within 1 month which required hospitalization		
Unilateral leg swelling		

- If **Yes** is answered for any question then PE **cannot** be ruled out of differential diagnosis

Intervention

Hestia Criteria

	Yes	No
1. Hemodynamically unstable? *		
2. Thrombolysis or embolectomy necessary?		
3. Active bleeding or high risk of bleeding? ±		
4. Oxygen supply to maintain oxygen saturation > 90% > 24 h?		
5. Pulmonary embolism diagnosed during anticoagulant treatment?		
6. Intravenous pain medication > 24 h?		
7. Medical or social reason for treatment in the hospital > 24 h?		
8. Creatinine clearance of less than 30 mL/min? ¤		
9. Severe liver impairment? ¶		
10. Pregnant?		
11. Documented history of heparin-induced thrombocytopenia?		

If one of the questions is answered with **YES**, the patient **CANNOT** be treated at home

* Include the following criteria, but leave these to the discretion of the clinician: systolic blood pressure < 100 mm Hg with heart rate > 100 beats/min; condition requiring admission to an intensive care unit
± Gastrointestinal bleeding in the preceding 14 days, recent stroke (< 4 weeks ago), recent operation (< 2 weeks ago), bleeding disorder or thrombocytopenia (platelet count < 75 x 10⁹/L), uncontrolled hypertension (systolic blood pressure > 180 mm Hg or diastolic blood pressure > 110 mm Hg)
¤ Calculated creatinine clearance according to the Cockcroft-Gault formula
¶ Left to the discretion of the physician

Intervention

Clinical Features of Acute PE Correlated for Mortality Risk

	Low Risk	Intermediate Risk ("submassive")	High Risk ("massive")
Hemodynamic status *	Normal	Normal	Unstable
Hypoxia	±	+	+++
Serum biomarkers	-	±	++
RV dysfunction ¥	-	+	+++

Key: - = normal; ± = may be present; ++ = likely present; +++ = present
* SBP < 90 mm Hg or decrease ≥ 40 mm Hg from baseline, or requires a vasopressor infusion
¥ RV dysfunction diagnostic criteria:
- Echocardiography or CT: RV/LV diameter ration ≥ 0.9 and/or RV systolic dysfunction
- Elevated cardiac biomarkers: BNP, NT-proBNP, and/or cardiac troponin
- ECG: New complete/incomplete right bundle branch block and/or anteroseptal ST-segment elevation/depression and/or anteroseptal T-wave inversion
BNP = B-type natriuretic peptid; LV = left ventricle; PE = pulmonary embolism; RV = right ventricle

Intervention

- Treatment Options (including class, dosing regimen, precautions, and interactions)
  - No-Bridge required
    - Eliquis (apixaban)
    - Xarelto (rivaroxaban)
  - Bridge required
    - Warfarin

Pre-intervention data

- Study period January 1, 2017-December 31, 2017
- Patients with diagnosis of PE Identified by ICD 10 code = 198
- Patients fitting inclusion criteria = 89
- Age range = 19-89 years old
- Mean age = 65.8 years old

- Insurance
  - Insured = 85
  - Uninsured = 4

Pre-intervention data

- Pre-test probability
- Wells Score
  - Positive = 67 (75.3%)
  - Negative = 22 (24.7%)
- PERC
  - Positive = 88 (98.9%)
  - Negative = 1 (1.1%)
- Additional risk stratification
  - D-Dimer performed = 30 (33.7%)
    - Negative on 1 patient captured and PE ruled out
  - CT performed = 79 (89%)
  - VQ performed = 6 (6.7%)

Pre-Intervention data

- Severity and mortality risk assessment
- Hestia
  - Qualify for outpatient treatment = Yes - 21 (23.6%), No – 68 (76.4%)
  - Received outpatient treatment = 8 (38% of those eligible)
  - Qualify for outpatient treatment and Low-risk = 8 (38% of eligible)
    - 3 patients treated outpatient
  - Qualify for outpatient treatment with massive/sub-massive = 13 (62% of eligible)
    - 4 patients treated outpatient
- Clinical features mortality risk
  - Low-risk = 26 (29.2%)
  - Massive/sub-massive = 63 (70.8%)

Pre-Intervention data

- Bleeding risk assessment
  - Average HAS-BLED for those that qualify for outpatient therapy = 1.23
  - Average HAS-BLED for those that do not qualify for outpatient therapy = 2.12
- Length of stay
  - Average length of stay for those that qualify for outpatient therapy = 1.2 days
  - Average length of stay for those that do not qualify for outpatient therapy = 4.22 days

Pre-Intervention data

- Re-admission within 30 days
  - 2 (2.3%) both admitted initially, 3 (3.4%) emergency visits not resulting in admit
- Recurrence
  - 1 Possible (1.1%), patient moved to hospice with no diagnostic scan
- Deaths within 30 days
  - 4 (4.5%) 3 did not discharge from initial encounter
- Deaths within 90 days
  - 6 (6.7%)
- Major bleed while on therapy
  - 5 (5.6%)
  - 4 patients (4.5%) visited emergency department or physician due to minor bleeds

Discussion

- Analysis of pre-intervention data
  - Validated tools selected for pre-test probability
  - Identified numerous patients that may have qualified for outpatient therapy
  - Showed a decreased average length of stay in patients admitted that qualified for outpatient therapy
  - Identified 0 patients that would have qualified for outpatient therapy that suffered re-admission, recurrence, major bleed, or death, which is in line with other studies and current guidelines.

Conclusion

- Current treatment practices of PE patients identified in the emergency department is safe and effective with a low incidence of re-admission, recurrence, major bleeding, and mortality.
- Adherence to the proposed intervention will likely help to identify more PE's earlier as well as identify low-risk patients utilizing validated tools which in turn will hopefully increase outpatient treatments, decrease admissions, and decrease cost associated with the treatment of PE.
- Limitations-
  - This study is retrospective and only captures patients that have a confirmed diagnosis of PE by ICD-10 code. This study is single center and may not represent patterns seen in other areas or settings.
  - As always when performing reviews within the electronic health record, incomplete documentation could skew data.

Future Directions

- Post-intervention data collection
- Continued reinforcement for use algorithm
- Continued education and resources as needed or as data becomes available
- If effective, pursuit to standardize process as approved protocol
- Possibly implement in outlying departments/clinics

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