

**1. Title Page:**

* Title: An Analysis of Risk Associated with Saddle Pulmonary Embolism (PE)-

A Retrospective Review

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* Protocol Version and Date: Version 1; 24 April 2018

**2. Abstract:**

Studies of adults with acute pulmonary embolism indicate that low risk patients on the pulmonary embolism severity index (PESI) and without clinical contraindications may be safely and effectively managed as an outpatient.

The most recent guidelines from The American College of Chest Physicians on antithrombotic therapy issued in 2016 render the quality of the evidence for treatment of acute PE at home a weak recommendation based on moderate quality evidence, indicating that ideal candidates lack clarity and consensus agreement.

The clinical course and prognostic implications of saddle pulmonary embolism diagnosed per CT pulmonary angiography remains controversial and therefore it is unknown as to whether the presence of saddle embolus should represent an exclusion for outpatient anticoagulant therapy.

It has not been established that traditional commonly used calculators validated to predict 30 day acute pulmonary embolism mortality can be specifically applied to all cohorts of patients with pulmonary embolism including those with saddle PE.

The primary aim of the study is to retrospectively evaluate the inpatient adverse event rates in low risk sPESI and PESI saddle PE patients. **These results will be compared to an age and severity matched cohort of a comparable number of patients with non-saddle PE's who were hospitalized at the same facilities during the same period of time.**

A secondary goal is to determine the prevalence of commonly accepted exclusion criteria that would preclude managing saddle PE patients in an outpatient setting.

**3. Introduction and Background:**

The ability to rapidly and accurately risk stratify patients with pulmonary embolism (PE) and the availability of direct oral anticoagulants have reduced the need for hospitalization in patients at low risk for complications. Although initiating anticoagulation on an outpatient basis has been shown to be safe, it remains an uncommon practice.

As many as 70 per cent of patients admitted to hospitals with PE may be suitable candidates for outpatient or early discharge (less than 2 days). Despite this, a recent retrospective review of 746 patients with PE who were potentially eligible for anticoagulation at home reported that only 1.7 % of patients were treated at home and only 16 % discharged within 2 days.

Although home management of select patients with acute PE is widely recommended and considered an evidenced based practice by the ACCP, European Society of Cardiology, and European Respiratory Society, no consensus of relative contraindications to outpatient treatment of PE has been established.

Inpatient care accounts for nearly one third of all US healthcare expenditures and limiting avoidable admissions represents a key target to optimize value of care.

A saddle pulmonary embolus is defined as a visible thromboembolism that straddles the bifurcation of the main pulmonary artery trunk. Saddle pulmonary emboli have been reported in 3 to 6 % of patients diagnosed with pulmonary embolism by CT pulmonary angiography. The clinical course and prognostic implications of saddle pulmonary embolus remains to be established.

Data exists indicating that saddle PE may not be an independent predictor of adverse outcome.

Risk stratification tools for acute PE function most optimally when used as a supportive, not a directive tool, in combination with clinical considerations.

Clinical variables that may serve as relative contraindications to outpatient management have not been definitively established but are critical to standardizing care.

There exists controversy as to whether saddle PE should be considered a relative contraindication to outpatient anticoagulation even when scored as low risk by a validated stratifying tool.

The PESI (pulmonary embolism severity index) is the most extensively validated clinical prediction model at identifying PE patients at low risk for 30-day mortality. The PESI records 11 clinical variables that are abstracted from admission entry data.

The sPESI (simplified pulmonary embolism severity index) records 6 clinical variables obtained routinely from admission entry data. It has not been prognostically validated but in a retrospective cohort of 995 patients with PE it yielded a similar prognostic accuracy as PESI in predicting 30 day mortality (sPESI 1%, PESI 3% for low risk scored patients)

Although PESI was not constructed specifically to predict 5 day inpatient decompensation it has performed well on this measure when augmented by significant clinical outpatient eligibility criteria with low risk scored subjects demonstrating adverse event rate of 1.2 % at 14 days.

**4. Objectives:**

1. Retrospectively assign PESI (pulmonary embolism severity index) and sPESI (simplified pulmonary embolism severity index) scoring to patients diagnosed with saddle PE and record the percentage of saddle PE patients that fall into a low risk category.
2. Determine the percentage of patients with saddle PE with relative contraindications to outpatient management defined as the patient meeting one of the following criteria: discharge requirement for supplemental oxygen, narcotics required for pain control, recent history of bleeding or risk factors for bleeding, abnormal mental status, pregnancy, lower extremity deep venous thrombosis (DVT), thrombocytopenia with platelet count less than 70k, or serious comorbid conditions including chronic heart, liver or renal disease.
3. Determine the percentage of patients with saddle PE who experienced a major adverse event while hospitalized defined as having any one of the following (adapted from Massachusetts General Hospital): death, need for CPR, use of electrical defibrillation, major hemorrhage, recurrent PE, use of vasopressors, use of ionotropes, new cardiac arrhythmia requiring treatment, urgent need of clot lysis because of severe hypoxemia or hemodynamic instability, or the need for respiratory support- use of nonrebreather (NRB) or mechanical ventilation.
4. Establish whether CT evidence of RV strain correlates with RV strain on Echocardiogram.
5. Calculate the PESI and sPESI scores for saddle pulmonary embolism for patients who required thrombolytic therapy during their hospitalization stay.

**5. Participant Selection:**

All patients > 18 years of age admitted to the Piedmont System since 2013 with an ICD code for saddle pulmonary embolism and confirmed by imaging on CT chest.

**6. Study Design and Methods:**

Retrospective chart review of all patients diagnosed with a saddle pulmonary thromboembolism (PE) within the Piedmont Health System (all hospitals) from 2013 to the present, **9/26/2018**.

We will confirm saddle PE by viewing images on CT chest for each patient. A saddle pulmonary embolus is defined as a visible thromboembolus that straddles the bifurcation of the main pulmonary artery trunk.

We will retrospectively collect the following information from the patient’s chart:

1. Age
2. Sex
3. BMI
4. Past Medical History (looking for history of cancer, heart failure, or chronic lung disease)
5. Admission Vital Signs: heart rate, systolic blood pressure, respiratory rate, temperature, oxygen saturation
6. Whether there was a change in mental status on admission (disorientation, lethargy, stupor, or coma)
7. EKG results
8. Assessment of RV (right ventricular strain) from Echocardiogram
9. Troponin
10. BNP
11. Results of lower extremity Doppler ultrasound if available
12. Length of Stay
13. All variables mentioned in Objective section above

**7. Informed Consent Process**:

N/A, Retrospective.

**8. Statistical Analysis:**

A statistician will analyze the retrospective data outlined in the protocol.

**9. Safety and Monitoring Reporting:**

Any unanticipated problems or adverse events (disclosure of PHI) will be promptly reported to the Piedmont Healthcare Institutional Review Board.

**10. Confidentiality**

De-identified data will be entered into a password protected database with access restricted to study investigators

**11. References/Bibliography**

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