Are you IN or OUT?
Outpatient Management of Low-Risk Pulmonary Embolism (LRPE) Patients

NOVEMBER 3, 2020
Disclaimers

This promotional educational activity is brought to you by Janssen Pharmaceuticals, Inc., and is not certified for continuing medical education. The consultant is a paid speaker for Janssen Pharmaceuticals, Inc. The speaker is presenting on behalf of Janssen Pharmaceuticals, Inc., and must present information in compliance with FDA requirements.

The protocols being shown were not created in collaboration with Janssen Pharmaceuticals, Inc.; they were created by the listed institution only. Janssen does not endorse or recommend the use of any particular protocol. These protocols are not intended to replace the independent medical or professional judgment of physicians or other healthcare providers.
Rachel P. Rosovsky, MD, MPH
Hematology
Massachusetts General – Boston, MA

Daren M. Beam, MD, MS
Emergency Medicine
Indiana University – Indianapolis, IN

Daniel R. Troha, MD, FACEP
Emergency Medicine
Atrium Health – Charlotte, NC
Agenda

- Prevalence of pulmonary embolism in the US
- Examples of low-risk PE protocols/algorithms
- Scoring tools for risk stratification
- Potential barriers to outpatient protocol development
RACHEL P. ROSOVSKY, MD, MPH
DIRECTOR, THROMBOSIS RESEARCH, DEPARTMENT OF HEMATOLOGY
MASSACHUSETTS GENERAL HOSPITAL
ASSISTANT PROFESSOR OF MEDICINE, HARVARD MEDICAL SCHOOL
Prevalence and Economic Burden of Pulmonary Embolism\textsuperscript{1,2}

\textbf{Annual VTE events occurring in the US}
\textbf{Annual economic burden}
\textbf{$\sim$900,000}
\textbf{> $8.5 billion}

PE = pulmonary embolism; VTE = venous thromboembolism.
1. CDC. VTE Data and Statistics. 2015.
Case

- 20-year old African American college junior presents to her institution's health services with two days of progressive right calf pain
- Pain so severe it is hard to walk
- Patient is told it is a muscle pull
  - use heat and ibuprofen, made follow-up for 3 days later
- The following evening patient became acutely short of breath
- Called back health services who advised she follow-up on her planned visit
Case continued

- Called her mother → ER
- She had started oral contraceptive 2 months prior
- She had family history of blood clots
- CT scan chest showed pulmonary embolus

Can she be treated as an outpatient?
Do all patients with DVT or PE need to be admitted?

Data behind outpatient treatment
Guideline Evidence for Outpatient Treatment of VTE

*20. In patients with low-risk PE and whose home circumstances are adequate, we suggest treatment at home or early discharge over standard discharge (eg, after the first 5 days of treatment) (Grade 2B).

- Clinically stable
- No contraindications
- Expected to be compliant with treatment
- Patient feels well enough to be treated at home and has support
- No presence of right ventricular dysfunction or increased cardiac biomarker levels
This algorithm has been developed for the speaker's institution using a multidisciplinary approach considering circumstances particular to specific patient populations, services and structure, and clinical information. This is not intended to replace the independent medical or professional judgment of physicians or other healthcare providers in the context of individual clinical circumstances to determine a patient's care. This algorithm should not be used to treat pregnant women.

CAD = coronary artery disease; CHF = congestive heart failure; US = ultrasound.
Outpatient treatment of DVT/PE

Timely follow up is most important component

- 2,212 patients

Follow-Up Clinic: Key Considerations

Every clinic is different. What will work for you?

✓ Needs
✓ Resources
✓ Existing clinic or new
✓ Multidisciplinary

Logistics

- Leader
- Administrative support
- Funding
- Schedule regular meetings to evaluate clinic
- Set up goals up front and readdress regularly

Structure

- How often
- Where
- Who
- When
- What
Follow-Up Clinic: Actions

**Follow-Up Care**

- Review clinical course
- Further work up
  - Inquiry into etiology of PE
- Address treatment
  - IVC filter; compression stockings
  - Anticoagulation
- Assess for new symptoms; screen for long-term complications

IVC = inferior vena cava

This material is being presented by healthcare professionals in collaboration with the American Medical Group Association. Speakers are paid consultants of Janssen Pharmaceuticals, Inc.
Follow-Up Clinic: Lesson Learned

- Schedule follow up clinic before discharge from ER; put in patient’s discharge summary
- Description of follow up in discharge summary
- Case manager check insurance if covered and if not, set up with local specialists (start with PCP)
- Letter to patient prior to appointment
- Call to patient prior to appointment
- Follow-up testing before clinic
Case Follow-Up
Take Home Message

- PE is a major cause of morbidity and mortality worldwide
- Evidence supports the treatment of low-risk PE in an outpatient setting
- Having a comprehensive and robust follow-up system for these patients is essential

Risk Stratification Tools

- PESI
- sPESI
- HESTIA
## Pulmonary Embolism Severity Index (PESI)

<table>
<thead>
<tr>
<th>Points assigned</th>
<th>Points assigned</th>
<th>PESI score</th>
<th>Class</th>
<th>Low vs high risk</th>
</tr>
</thead>
<tbody>
<tr>
<td>Age</td>
<td>Age in years</td>
<td>Pulse ≥110 min</td>
<td>+20</td>
<td>≤65</td>
</tr>
<tr>
<td>Male sex</td>
<td>+10</td>
<td>SBP &lt;100 mm Hg</td>
<td>+30</td>
<td>66-85</td>
</tr>
<tr>
<td>Cancer</td>
<td>+30</td>
<td>Resp rate ≥30</td>
<td>+20</td>
<td>86-105</td>
</tr>
<tr>
<td>Heart failure</td>
<td>+10</td>
<td>Temp &lt;36°C</td>
<td>+20</td>
<td>106-125</td>
</tr>
<tr>
<td>Chronic lung disease</td>
<td>+10</td>
<td>Altered mental status</td>
<td>+60</td>
<td>&gt;125</td>
</tr>
<tr>
<td></td>
<td></td>
<td>O₂ sat &lt;90%</td>
<td>+20</td>
<td></td>
</tr>
</tbody>
</table>


This material is being presented by healthcare professionals in collaboration with the American Medical Group Association. Speakers are paid consultants of Janssen Pharmaceuticals, Inc.
Simplified PESI (sPESI)

0, low risk. 1 or more, high risk.

- Age >80 years
- History of cancer
- History of heart failure or chronic lung disease
- Pulse >110 beats/min
- SBP <100 mm Hg
- $O_2$ sat <90%

Identifies low-risk PE if

- Not hemodynamically unstable
- No thrombolysis or embolectomy necessary
- Not actively bleeding or at high risk of bleeding
- $O_2$ saturation >90%*
- No PE diagnosed during anticoagulation

- No pain requiring IV meds for >24 hours
- No medical or social reason for treatment in the hospital for >24 hours
- Creatinine clearance ≥30 mL/min
- No severe liver impairment
- No pregnancy
- No documented history of HIT

* Not requiring >24 hours on supplemental oxygen to maintain. HIT = heparin-induced thrombocytopenia.

A survey of IU Health faculty showed:

- 42% Follow up*
- 40% I’ve never done it before/too unfamiliar
- 33% A DOAC might be too expensive
- 24% I’m worried about medico-legal liability*
- 21% I still feel more comfortable if they are hospitalized
- 21% It’s easier to admit them than discharge

* Percentages are rounded to the nearest whole number.

How is a patient referred to the Clot Clinic?

Positive CT pulmonary angiogram

**Pulmonary Embolism**
- Normotensive
- No RV strain
- No abnormal biomarkers

**Risk Stratify**

HESTIA, PESI, sPESI

Low-risk
- Consider Home Treatment

High-risk
- Admit

PCP

Clot Clinic

This algorithm has been developed for the speaker's institution using a multidisciplinary approach considering circumstances particular to specific patient populations, services and structure, and clinical information. This is not intended to replace the independent medical or professional judgment of physicians or other healthcare providers in the context of individual clinical circumstances to determine a patient's care. This algorithm should not be used to treat pregnant women.

This material is being presented by healthcare professionals in collaboration with the American Medical Group Association. Speakers are paid consultants of Janssen Pharmaceuticals, Inc.
Emboli (Clot) Clinic

- Operated at two hospitals
- Referral clinic from area EDs
- One operated by Nurse Practitioners and one operated by Pharmacists
- Patients seen 2-5 weeks after diagnosis

Metrics
- >700 patients seen (354 Methodist alone)
- ~25% pulmonary embolism
- If determined life-long anticoagulation, patient transitioned to primary care

Key Learnings at IU

- Outpatient treatment is now feasible
- Safety has already been demonstrated
- Patient satisfaction is increased
- Costs are lower


This material is being presented by healthcare professionals in collaboration with the American Medical Group Association. Speakers are paid consultants of Janssen Pharmaceuticals, Inc.
Multidisciplinary Teams Are A Must

- Emergency Department was main driver, but it took a multidisciplinary team to make it work
  - Hematology
  - Pharmacy
  - Transition (Outpatient) Clinic
  - Internal Medicine
Outpatient PE Protocol Example

POWER PLAN ACTIVATES:
• Pharmacy: generates a 30-day prescription and free trial card
• Transition Clinic: Prompts staff to make call within 72 hours to schedule patient for follow-up appointment

MED DELIVERY ENSURES:
• Patient can leave ED with 30-days worth of medication*: Outpatient pharmacy delivers within 1 hour to ED or patient given To-Go Pack
• Patient gets same level of care regardless of hospital site

*Unless picking up at retail pharmacy upon discharge.

This algorithm has been developed for the speaker’s institution using a multidisciplinary approach considering circumstances particular to specific patient populations, services and structure, and clinical information. This is not intended to replace the independent medical or professional judgment of physicians or other healthcare providers in the context of individual clinical circumstances to determine a patient’s care. This algorithm should not be used to treat pregnant women.

This material is being presented by healthcare professionals in collaboration with the American Medical Group Association. Speakers are paid consultants of Janssen Pharmaceuticals, Inc.
Patient Case – LM

**History of Present Illness**
LM is a 57 y/o male who presents to the ED with chest pain and shortness of breath.

**Vital Signs**
- BP: 125/82
- HR: 95
- RR: 16
- \(O_2\) sat: 96% RA

**Labs**
- No abnormal biomarkers
- Scr: 0.7
- No elevated LFTs
- Platelets: 175 x 10^9/L

**Imaging**
- Positive CTPA
Patient Case - LM

If LM presents to a main hospital ED…

If LM presents to a freestanding ED…

30-day supply filled and delivered within 1 hour to ED

Patient discharged with

To-Go Packs from ED Omnicells

Patient discharged with

Outpatient Pharmacy

Hospital

ED in rural area
Protocol Outcomes

- Protocol is active at 15 Emergency Departments within the health system
- Approximately 1,000 patients have been treated
- Extremely low rates of recurrent VTE and bleeding episodes requiring hospitalization*

*Of 947 patients treated, 9 experienced recurrent VTE and 11 experienced bleeding that required hospitalization.
Thank You!

This material is being presented by healthcare professionals in collaboration with the American Medical Group Association. Speakers are paid consultants of Janssen Pharmaceuticals, Inc.