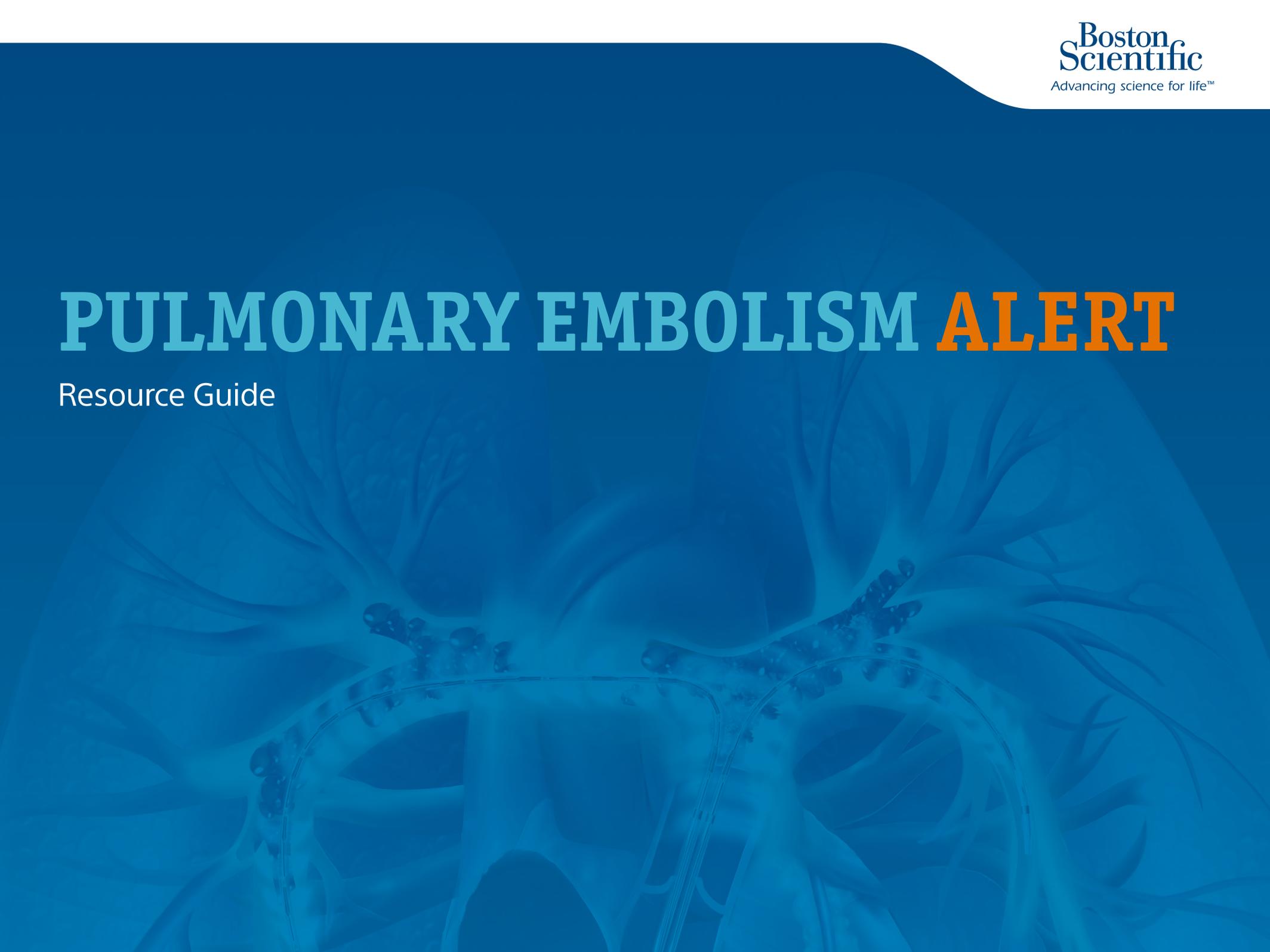


PULMONARY EMBOLISM **ALERT**

Resource Guide



Boston Scientific Corporation is committed to advancing the treatment of acute pulmonary embolism (PE). Through technological innovation, such as EKOS™ Acoustic Pulse Thrombolysis treatment, and a comprehensive approach to clinical research, we are dedicated to improving patient outcomes.

Our approach, however, extends beyond devices – our goal is to be your ally in improving the patient treatment pathway, from onset to recovery. The Boston Scientific Team looks forward to partnering to support the development of a series of programs to help your facility treat PE patients more safely and effectively.

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PULMONARY EMBOLISM ALERT

What is Acute Pulmonary Embolism?

PE is a condition in which a blood clot breaks off from the deep veins of the leg, groin or arm (deep vein thrombosis or DVT) and travels in the circulatory system to the pulmonary arteries where they can block blood flow and access to the lungs' vital oxygenation system. In intermediate-risk or high-risk cases, this may lead to a strain on the heart's ability to pump blood through the lungs which can then lead to heart failure and/or cardiovascular collapse.

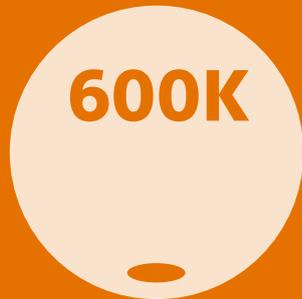
Common PE symptoms include:

- Shortness of breath
- Progressively worsening chest pain
- Cough
- Clammy or discolored skin
- Excessive sweating
- Rapid or irregular heartbeat
- Lightheadedness or dizziness



PE can be immediately fatal. However, if PE can be diagnosed and appropriate therapy started, the mortality can be reduced from approximately 30 percent to less than 10 percent.¹

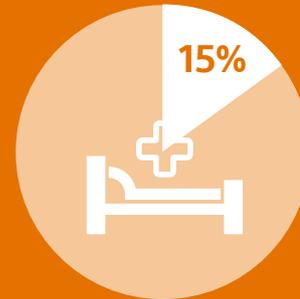
The Impact of Pulmonary Embolism



Over 600,000 patients annually in the US. Less than 4% treated interventionally²



Causes more deaths in the US each year than Car accidents, Cancer and AIDS combined³



Is the cause of or contributes to 15% of all hospital deaths⁴



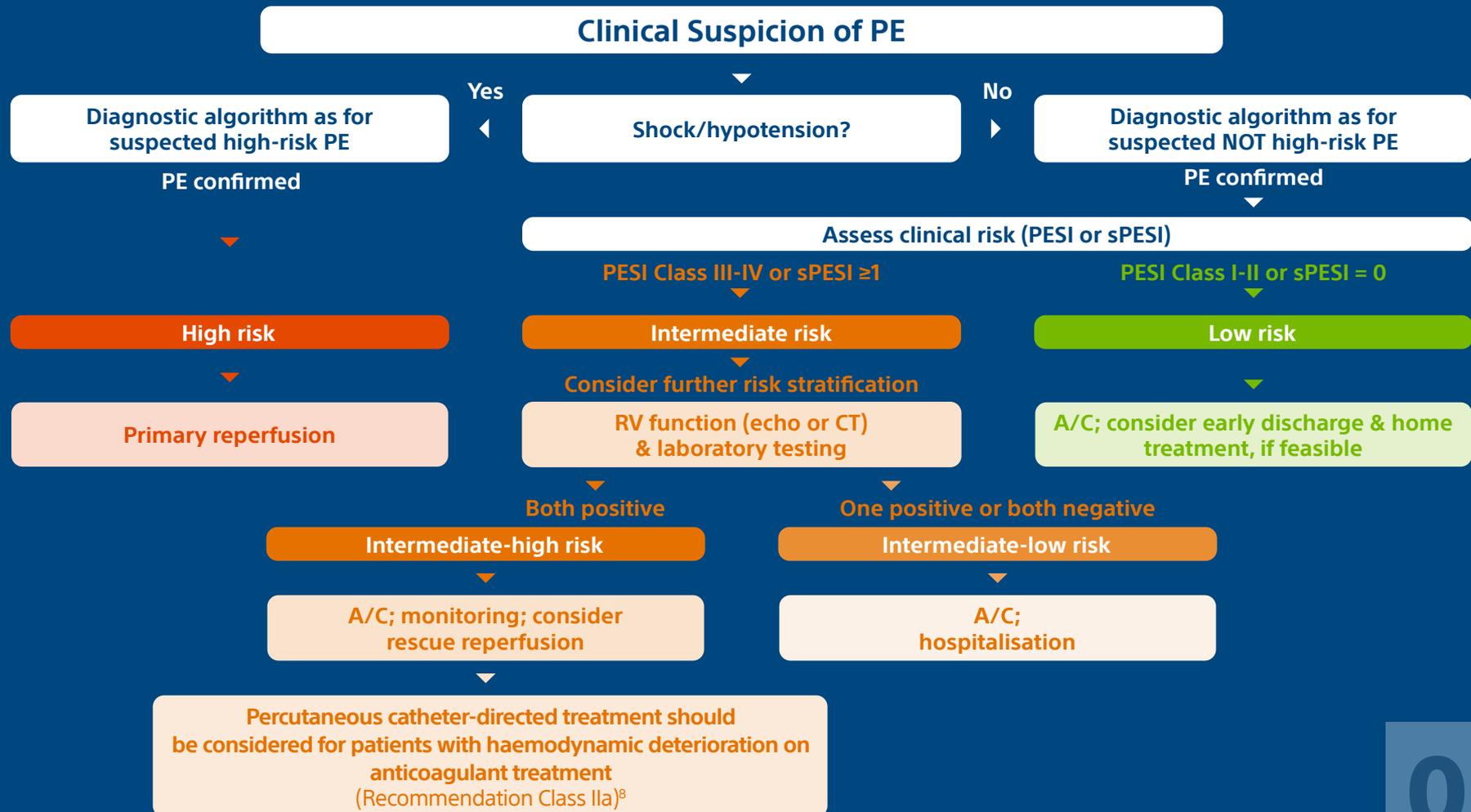
79% of patients presenting with PE have evidence of DVT^{5,6}

PE occurs in up to 50% of patients with proximal DVT⁷

VTE: Venous thromboembolism (PE + DVT)

The Diagnosis and Management of Acute PE

The following patient risk stratification and treatment algorithm is adapted from the 2019 European Society of Cardiology (ESC) Guidelines.⁸



Why Intervene on Intermediate-Risk PE Patients?

Various studies report the presence of right ventricular dysfunction (RVD) as a predictor of poor clinical outcomes:

- The presence of RVD on the baseline echo is associated with higher mortality at 2 weeks and 3 months compared to cases with no RVD.⁹
- RVD is associated with **57% higher mortality rate at 3 months**, even in the absence of hemodynamic instability.⁹
- RV/LV >0.9 is an independent predictor of mortality. **Mortality risks increase step-wise as RV/LV increases.**^{10,11}
- Patients with RVD defined as **RV/LV >0.9** have a **greater chance of adverse events within 30 days** than those with $RV/LV \leq 0.9$.¹²
- Patients with unresolved RVD are **8 times more likely to experience recurrent venous thromboembolism (VTE)** than those without RVD.¹³

 **RV/LV**
> 0.9



**Mortality
Adverse Events
VTE Recurrence**

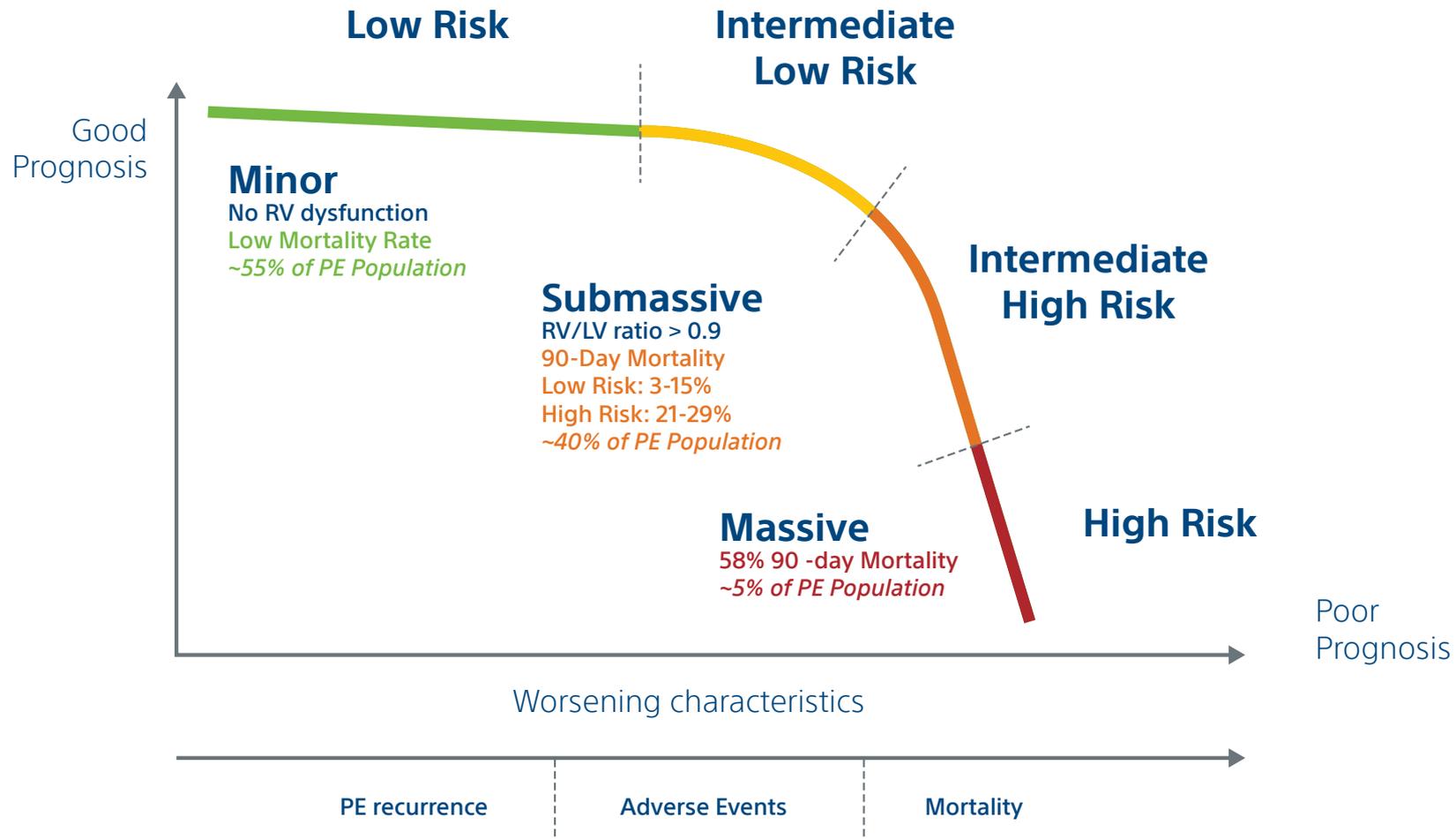
57%

Higher Mortality
at 3 months

8x

higher likelihood
of recurrence

PE Patient Risk Stratification¹⁴



RV dysfunction is a predictor of poor clinical outcomes

Developing a Successful PE Program

PE Alert Checklist

Early identification is a vital initial step in the emergency medical management of PE. A symptoms-based screening tool facilitates rapid, standardized clinical assessment. Based on the assessment, routing the acute PE patient to the most appropriate treatment facility which offers clinically robust interventional technologies, including the EKOS™ system, will improve outcomes for patients.

Establishing PE Patient Pathway

In order to facilitate a rapid, robust response to the diagnosis of PE it is important to implement a standardized PE Pathway.

The PERT model is based on existing multidisciplinary teams such as heart teams and rapid response teams. A PE program can involve clinicians from the range of specialties involved in the treatment of PE, including pulmonology, critical care, interventional radiology, cardiology and vascular surgery among others.

The team serves as a consult service that is able to provide expert advice on the initial management of PE patients and convene in real time to develop a consensus treatment plan specifically tailored to the needs of a particular patient and consistent with the capabilities of the institution.¹⁵

Example Pulmonary Embolism Response Team (PERT)



Specialties Involved in the PE Patient Pathway

Assessment of the status of a PE patient and decision on treatment is a multidisciplinary approach. Building a comprehensive PE program should be a collaborative effort and consider measures of quality, resource utilization, efficiency, and market development. Benefits of committing to a PE program include the ability to better serve the community and bring more patients into the institution.

Pulmonologist, Emergency Medicine, Internal Medicine and Vascular Medicine

Depending on the patient situation at onset, i.e. coming into the Emergency Department or already admitted to the hospital because of comorbidities, several clinicians are included in the decision-making process. To facilitate an easier decision-making process, a multidisciplinary approach has been shown to be beneficial to the patient. In this way, protocols have been prepared and discussed prior to the arrival of an acute PE patient.

Interventional Radiologist, Interventional Cardiologist, and Vascular Surgeon

Placement of the EKOS™ Device is usually done by an interventionalist. The procedure is carried out in the cath lab or angio lab under fluoroscopy.

Other Specialties

Orthopedists, Hematologists, and Oncologists can see patients who develop a PE due to the patient disease. They refer patients to the ICU or they can activate the Pulmonary Embolism Response Team.

Administrators and Executives

Caring for patients suffering from PE takes a concerted effort of medical specialties to optimize patient care. In order to have a successful PE program, administrators must consider the following:

Manpower

Imaging and angiography

Intensive Care Unit

Program Awareness



07

Professional Education

Access to Care Programs

Access to Care Programs are held to strengthen the relationship between the different teams in the Pulmonary Embolism care chain of your hospital. The development of local networks that link primary care hospitals and physicians to comprehensive pulmonary embolism centers can help to improve patient outcomes.

Education Topics:

- Patient Pathway
- Protocol Discussion
- Treatment Options
- Patient Selection
- Resource Overview
- Case Discussions
- Summary of Clinical Data

Medical Education

Boston Scientific EDUCARE is a comprehensive suite of education and training programs that support healthcare professionals in the delivery of patient care worldwide.

We offer innovative procedural simulations and learning programs with globally-recognized faculty.

Continuing Education Units

The CE Program is intended for registered nurses and radiologic technologists. Delivered either virtually or live, these 50 minute programs are held by your local Boston Scientific Representative. One contact hour will be recorded for each CE program attended.

Boston Scientific Innovation Center Visit

The Innovation Center is located at Boston Scientific's divisional headquarters in Minnesota. This program provides an opportunity to discuss current and future BSC product technologies and solutions with BSC leadership, Marketing, and R&D partners.

Please contact your Boston Scientific Representative for more information.

1. Banovac, R., et al., "Reporting standards for endovascular treatment of pulmonary embolism." *J Vasc Interv Radiol*, 2010; 21: 44-53. X
2. Wood KE et al. Major pulmonary embolism: review of a pathphysiologic approach to the golden hour of hemodynamically significant pulmonary embolism. *Chest* 2002;121:877-905.
3. "Deep Vein Thrombosis: Advancing Awareness to Protect Patient Lives." Public Health Leadership Conf. Feb 2003, American Public Health Association.
4. Beers, M.H., et al., *The Merck Manual of Diagnosis and Therapy. 18th edition*. Whitehouse Station, NJ: Merck Research Laboratories, 2006: 412-22, 427, 2081-2.
5. Tapson, V.F., "Acute pulmonary embolism." *N Engl J Med*, 2008; 358(10): 1037-52.
6. Sandler, D.A., et al., "Autopsy proven pulmonary embolism in hospital patients: are we detecting enough deep vein thrombosis?" *J R Soc Med*, 1989; 82: 203-5.
7. Huisman, M.V., et al., "Unexpected high prevalence of silent pulmonary embolism in patients with deep venous thrombosis." *Chest*, 1989; 95(3): 498-502.
8. Konstantinides, S.V., et al. 2019 ESC Guidelines for the diagnosis and management of acute pulmonary embolism developed in collaboration with the European Respiratory Society (ERS). *Eur Heart J*, 2020; 41:543-603
9. Goldhaber SZ, Visani L, De Rosa M. Acute pulmonary embolism: clinical outcomes in the International Cooperative Pulmonary Embolism Registry (ICOPER). *Lancet (London, England)*. 1999;353(9162):1386-1389.
10. Fremont et al. Prognostic Value of Echocardiographic Right/Left Ventricular End-Diastolic Diameter Ratio in Patients with Acute Pulmonary Embolism. *CHEST* 2008; 133:358-362.
11. van der Meer RW, Pattynama PM, van Strijen MJ, et al. Right ventricular dysfunction and pulmonary obstruction index at helical CT: prediction of clinical outcome during 3-month follow-up in patients with acute pulmonary embolism. *Radiology*. 2005;235(3):798-803.
12. Kucher N, Boekstegers P, Müller OJ, et al. Randomized, controlled trial of ultrasound-assisted catheter-directed thrombolysis for acute intermediate-risk pulmonary embolism. *Circulation*. 2014;129(4):479-486.
13. Grifoni S, Vanni S, Magazzini S, et al. Association of persistent right ventricular dysfunction at hospital discharge after acute pulmonary embolism with recurrent thromboembolic events. *Arch Intern Med* 2006; 166:2151-2156.
14. Goldhaber S, Visani L, DeRosa M. Acute pulmonary embolism: clinical outcomes in the International Cooperative Pulmonary Embolism Registry (ICOPER). *The Lancet*; Apr 24,1999; 353,9162; Health Module pg. 1386.
15. Root, C.W., et al. "Multidisciplinary approach to the management of pulmonary embolism patients: The pulmonary embolism response team (PERT)". *J Multidiscip Healthc*, 2018; 11: 187-95 .

Abbreviations

- A/C:** Anticoagulation
- CDT:** Catheter-directed therapy
- CT:** Computed tomography
- DVT:** Deep vein thrombosis
- ICH:** Intracranial haemorrhage
- ICU:** Intensive care unit
- LV:** Left ventricle/ventricular
- PE:** Pulmonary embolism
- PERT:** Pulmonary embolism response team
- PESI:** Pulmonary embolism severity index
- RV:** Right ventricle/ventricular
- RVD:** Right ventricular dysfunction
- sPESI:** Simplified pulmonary embolism severity index
- VTE:** Venous thromboembolism

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