

DOI: 10.36648/2471-8157.7.8.145

The Research Differentiation of Interventional Pulmonary Embolism Therapy in Combination with Anticoagulation to Anticoagulation

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Received: August 03, 2021; Accepted: August 17, 2021; Published: August 24, 2021

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Citation: Mizrahi S (2021) The Research Differentiation of Interventional Pulmonary Embolism Therapy in Combination with Anticoagulation to Anticoagulation. *Interv Cardiol J* Vol.7 No.8:145

Pulmonary embolism (PE) represents the third leading cause of cardiovascular mortality. The technological landscape for management of acute intermediate- and high-risk PE is rapidly evolving. Two interventional devices using pharmacomechanical means to reanalyse the pulmonary arteries have recently been cleared by the US Food and Drug Administration for marketing, and several others are in various stages of development. The purpose of this document is to clarify the current state of endovascular interventional therapy for acute PE and to provide considerations for evidence development for new devices that will define which patients with PE would derive the greatest net benefit from their use in various clinical settings. First, definitions and limitations of commonly used risk stratification tools for PE are reviewed. An adjudication of risks and benefits of available interventional therapies for PE follows. Next, considerations for optimal future evidence development in this field are presented in the context of the current US regulatory framework. Finally, the document concludes with a discussion of the pros and cons of the rapidly expanding PE response team model of care delivery.

Venous thromboembolism (VTE) is an illness that has a potentially life-threatening condition that affects a large percentage of the global population [1]. VTE with pulmonary embolism (PE) is the third leading cause of death after myocardial infarction and stroke. In the first three months after an acute PE, there is an estimated 15% mortality among sub massive PE, and 68% mortality in massive PE. Current guidelines suggest fibrinolytic therapy regarding the clinical severity; however some studies suggest a more aggressive treatment approach. This review will summarize the available endovascular treatments and the different techniques with its indications and outcomes. Since there are a variety of CDT and Thrombectomy methods, more prospective studies are still needed to refine the interventional approach protocol and determine the safest techniques in larger cohorts. This review will outline the different clinical presentation of PE, and will summarize the available endovascular treatments and the different techniques with its indications and outcomes. The incidence of venous thromboembolism (VTE), including pulmonary embolism (PE) and deep venous thromboembolism (DVT), in the United States is unclear because there is no national surveillance system. However, PE is considered to be the third most common cause of cardiovascular death, with 60,000-100,000 deaths per year. This is likely an underestimation because PE can result in unexplained sudden cardiac death. Treatment varies depending on the severity of the disease and

the centre's expertise and resources [2]. A consensus document was recently issued by the Pulmonary Embolism Response Team (PERT) Consortium, which endorses a PERT approach to high and intermediate-risk cases by a multidisciplinary team. This team includes, but is not limited to, cardiac surgery, cardiology, haematology, critical care, vascular medicine, vascular surgery, and radiology specialists who discuss complex cases and expedite treatment decisions.

Venous thromboembolic disease (VTE) is estimated to occur in at least 1 to 2 persons per 1000 population annually, manifesting as deep vein thrombosis (DVT), pulmonary embolism (PE) or in combination. It is the cause of over 100,000 deaths annually and is the most preventable cause of death in hospitalized patients in the United States. Despite treatment with anticoagulant therapy, a significant proportion of survivors of acute DVT or PE are at risk of suffering from the disabling sequelae such as the post thrombotic syndrome (PTS), recurrent VTE or chronic thromboembolic pulmonary hypertension (CTEPH) [3]. Given the limitations of medical therapy, promising endovascular treatment modalities have evolved over the past two decades in an effort to mitigate the acute and chronic disability from VTE. The purpose of this review is to discuss the rationale and evidence for an endovascular treatment approach for high-risk acute DVT and PE patients. The most dreaded acute complication of PE is death; it is estimated that over 100,000 deaths in hospitalized patients in the United States are attributable to acute PE each year. The severity of PE is stratified into massive (PE causing hemodynamic compromise), sub massive (PE causing right ventricular dysfunction demonstrable by echocardiography, computed tomography or elevated cardiac biomarkers) and non-

massive or low-risk (PE without evidence of RV dysfunction or hemodynamic compromise).

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