PANEL DISCUSSION

Early PE-TRACT Enrollment Experiences

PE-TRACT trial investigators discuss roles and responsibilities, enrolling and randomizing patients, strategies to ensure follow-up compliance, and how the trial affects their PERT practices.

With Nancy Amoroso, MD, and Bedros Taslakian, MD, EBIR, FCIRSE

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First, please tell us about the PE-TRACT trial and your roles and responsibilities as investigators.

Dr. Taslakian: PE-TRACT is a multicenter randomized trial independently funded by the National Institutes of Health. The trial will evaluate the potential long-term benefits of catheter-directed therapy for submassive (intermediate-risk) pulmonary embolism (PE). As a site Principal Investigator (PI) at NYU Langone Health, I am responsible for the execution and conduct of this clinical study at three satellite sites: NYU Langone Manhattan, NYU Langone Brooklyn, and NYU Langone Long Island. In collaboration with our investigators and clinical study coordinator, my primary duties involve study oversight and leadership, quality assurance and data integrity, regulatory compliance and reporting, and communication and dissemination across our sites.

Dr. Amoroso: I am a Co-Investigator for the PE-TRACT trial. I am involved in screening and enrolling patients. I also make sure the patient is set up for appropriate clinical and research study follow-up prior to discharge, in coordination with the research nurse.

For those who have not participated in a trial like PE-TRACT, what are some of the details of becoming a trial site?

Dr. Taslakian: The first step is to express interest by contacting the clinical coordination center (CCC) to inquire about the requirements and eligibility criteria. The CCC then evaluates the site's potential suitability based on different factors such as patient population, facilities, and investigators' expertise. If the initial evaluation is favorable, the site undergoes a more thorough qualification process, followed by obtaining regulatory approvals from its institutional review board and/or ethics committee. The site then enters a formal contract with the study sponsor, and an investigative team is assembled. This team should include a site PI with expertise in PE and strong leadership skills. Each site must identify and credential at least one medical and one endovascular investigator, along with a research coordinator, to meet the essential requirements for site

activation. The site then receives training on the study protocol, data collection procedures, and regulatory compliance requirements. The CCC has established rigorous and detailed strategies and guidance for sites, including regular webinars and meetings for site investigators and coordinators.

What goes into enrolling and randomizing a patient in PE-TRACT?

Dr. Amoroso: Through our PE response team (PERT) and electronic medical record–generated report, we have a robust and organized system of identifying patients with PE, and we strive to capture every patient with a PE for review. Screening involves a critical review of the chart, including the clinical presentation, data, and imaging. This review allows us to determine if the patient meets inclusion and/or exclusion criteria. Our screening team consists of our research nurse, pulmonary/critical care physicians, and interventional radiologists. The screening happens in real time, and the approach is coordinated when multiple team members can be present. Time is spent with the patient to explain their diagnosis of PE, how we classify PE, and the potential treatment options. We also include family members, friends, or trusted physicians of the patient in this conversation at the patient's request. If the patient agrees to participate, they sign informed consent and enroll in the trial.

It is important that the approach happens when the investigative team has time to address questions. Often, a potential participant will want additional time to consider the enrollment. A second visit is sometimes required for follow-up questions before consent is signed.

Dr. Taslakian: As Dr. Amoroso said, the PE-TRACT study team has a patient-centered approach to enrollment. We ensure potential participants are adequately rested and stabilized and have a comprehensive understanding of their condition before engaging in the enrollment process. Enrolling and randomizing patients is a collaborative effort that involves the site investigative team, the research coordinator(s), the clinical teams, and the PE-TRACT study team. This ensures patient safety, ethical conduct, and adherence to the study protocol. In addition to the screening tools Dr. Amoroso detailed, sites may potentially use artificial intelligence systems.

In the informed consent process, patients are guided through comprehensive information about the trial's objectives, potential risks and benefits, and the voluntary nature of participation. They are encouraged to ask questions, seek clarifications, and engage in open dialogue to ensure they are fully informed and empowered to make an informed decision about their participation. If a patient expresses interest in exploring alternative treatment options beyond participation in the clinical trial, the research team respectfully defers to the clinical team, ensuring that patients receive unbiased and accurate information to make informed decisions about their health care.

Unbiased randomization is accomplished through an automated system that assigns participants to either anticoagulation therapy alone or catheter-directed therapy in combination with anticoagulation.

What enrollment challenges have you faced?

Dr. Taslakian: PE, especially intermediate-risk PE, is a complex condition exhibiting a wide spectrum of severity, with potential long-term implications. Patients often face a sudden and severe illness, leaving them understandably in a state of shock, anxiety, and emotional distress. This vulnerability, coupled with the inherent complexity of clinical trial participation, particularly randomization, necessitates a delicate approach that prioritizes patient-centered care. By allowing patients adequate time to rest, stabilize, and comprehend their condition before considering trial participation, we can ensure that the informed consent process is conducted with the utmost respect for patient well-being and autonomy. Furthermore, our investigators allow the clinical team to make the best clinical decision for the patient based on their clinical status. This ensures that patients are stable and ready to consider the trial before being approached by the study team.

Dr. Amoroso: Having patients be comfortable with randomization is challenging. One arm is invasive and involves a catheter-based procedure, while the other arm is noninvasive and involves medication only. Patients often hope for one treatment over the other, and as a result, they don't wish to be randomized. However, randomization is part of the scientific process we need to follow, and patients don't get to choose which arm they will be assigned to. Patients need to be educated to trust the process, and they are assured of the checks and balances built in for patient safety.

What is your strategy to retain patients for the length of the trial (compliance for their cardiopulmonary exercise testing at 3 months, other assessments at 1 year, etc)?

Dr. Amoroso: Standard practice is to monitor patients closely for the first year after PE, and sometimes longer. We reinforce that the patient will need to be followed both clinically and as part of the research study. Some of the tests that we do for the study will give additional information to allow the clinicians to take even better care of the patients.

Dr. Taslakian: To effectively retain participants, we have implemented a comprehensive strategy that prioritizes patient engagement. This strategy includes regular communication and updates, addressing concerns promptly, personalized support, building rapport and trust, patient feedback mechanisms, and ongoing training and support for research staff.

How has being a site for PE-TRACT affected your PE practice? The operations of the PERT?

Dr. Taslakian: Our institution has a well-established and highly effective PERT, comprising expert intensive care physicians, pulmonologists, cardiothoracic surgeons, cardiologists, and interventional radiologists. Participating as a site for the PE-TRACT trial has only further enhanced our collaboration, PE practice, and the operations of our PERT.

Dr. Amoroso: The PERT at NYU started in 2015 to standardize the treatment approach for PE and identify high-risk patients who may benefit from more intense multidisciplinary discussions and advanced therapies. Being a site has allowed for more in-depth collaboration between critical care and interventional radiology, has fostered shared decision-making with our patients, and has generated ideas about future projects.

Has your institution benefited from being a clinical trial site for PE-TRACT? If so, how?

Dr. Amoroso: Yes, it has allowed us to participate in the advancement of PE care for our patients.

Dr. Taslakian: Participation in the PE-TRACT trial has strengthened our research expertise and infrastructure. The emphasis on multidisciplinary collaboration has fostered stronger relationships among our institution's PE care providers and PERT members, leading to more comprehensive and coordinated patient management. The trial has also provided our investigators with valuable education and training opportunities in current PE diagnosis and treatment. This enhanced capacity has positioned us well to participate in future clinical trials. ■

Disclosures
Dr. Amoroso: None.
Dr. Taslakian: None.