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A discussion on current DVT therapies and how to achieve optimal outcomes for each patient.

How would you briefly describe the data landscape pertaining to deep vein thrombosis (DVT) therapies?

Almost 20 years after the initial report by Drs. Semba and Dake, the data landscape regarding catheter-based interventions for clot removal is still bare. Although there are numerous reports on the adjunctive use of thrombolysis in patients with DVT, the level of evidence as to the best initial therapy for these patients remains low.

Interestingly, the same is not true for anticoagulation alone, which is a very data-rich field. Many new and improved anticoagulants are on the horizon, with trials addressing both prophylactic and active treatment primary endpoints. Although these studies have and will continue to add to the quantity and quality of data for anticoagulation, the fundamental question of whether initial clot removal should be used as an adjunct to anticoagulation remains unanswered. The hope is that the ATTRACT trial will address this uncertainty.

What are the goals of the ATTRACT trial, and what is your role in it?

The framework of this study was put together by Principal Investigator Dr. Suresh Vedantham. ATTRACT is funded by the National Heart, Lung, and Blood Institute and is a phase 3, prospective, multicenter, randomized trial of patients with proximal DVT. The primary objective of ATTRACT is to establish whether percutaneous catheter-based therapies for proximal DVT prevent postthrombotic syndrome (PTS) and improve health-related quality of life with acceptable safety and costs. PTS is a disabling complication of proximal DVT that occurs in 25% to 50% of patients. There are also several clinically relevant secondary endpoints including severity of PTS, speed of symptom relief, quality of life, and economic parameters, among others. I am a member of the Steering Committee of this trial and chair of its Interventional Committee. Our center at St. Joseph Hospital Heart and Vascular Center in Orange, California also participates in the study.

Based on the current data and experiences, how should clinicians formulate decisions on which treatment to offer their DVT patients?

Keeping in mind that there remains significant uncertainty and clinical equipoise among physicians regarding the best initial treatment for proximal DVT, we strongly recommend the first-line use of percutaneous catheter-based therapies in appropriate patients with proximal DVT. This is based on the favorable safety and efficacy outcomes of current interventional therapies and the poor outcomes of anticoagulation in preventing PTS in patients with extensive proximal DVT.

What are some of the most important things you have learned about preventing PTS?

PTS is a common and often disabling complication of proximal DVT (clot in the iliofemoral segments). Our experience and that of others suggest that early removal of a clot improves venous outflow from the limb and prevents valvular damage. This reduces the risk of venous hypertension, which is the main cause of PTS. We now have to prove this to our colleagues outside of the interventional arena.

Which DVT patients would you categorically say are not candidates for mechanical thrombectomy of any kind? Which treatment options would you recommend for these patients?

Mechanical thrombectomy can be performed in almost all patients with DVT. The problem is that the current generation of devices is not very effective as a stand-alone therapy in the majority of cases. Limitations on who should be treated include patients with extensive thrombosis in the popliteal vein and inferior vena cava (IVC). Once the clot is removed, patency must be maintained by having good inflow and outflow. Mechanical devices cannot physically remove clots below the level of the sheath entry, and therefore, these patients will require thrombolysis. These devices are often used for debulking clots before or cleaning residual thrombus after pharmacological thrombolysis. Depending on the mode of action, patients with renal insufficiency would not be good candidates for devices causing hemolysis.

Do you view today's mechanical thrombectomy options as complementary, interchangeable, or hierarchical in terms of what they can do?

We should differentiate between the devices intended to work without thrombolytic agents and those that only

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work with drugs. The former being the percutaneous mechanical thrombectomy devices and latter being the lytic-assisted devices. For the purpose of treating DVT, it is rare for the current percutaneous mechanical thrombectomy devices to work without lytics. These devices were intended to compete with each other and are presumably interchangeable. In practice, however, some work faster and more effectively than others and hence are not really interchangeable. Their clot debulking or cleanup functions can be complementary to lytic-assisted devices. The efficacy of the sequential use of these various devices has never been rigorously studied, and therefore, their hierarchical value is unknown.

How would you describe the use of IVC filters in your practice? Has this changed at all during the past year or two?

This is a very important question with potential public health and economic implications. Although we adhere to the classic indications for the placement of IVC filters, our practice has grown in recent years, mostly driven by the increasing number of oncologic or elderly patients with DVT. The growth seen in the number of filters placed in recent years in the United States is additionally fueled by several other factors such as the introduction of optional filters, more widespread adoption of prophylactic indications, and aggressive marketing strategies on the part of some manufacturers. I would be curious to know if the increased use of IVC filters translates into a proportional reduced incidence of pulmonary embolism. Interestingly, there are data accumulating against the prophylactic use of IVC filters, suggesting that the practice may not be as beneficial as we think.

What are the roles of interventional therapies in patients with pulmonary embolism (PE)?

The current indication for thrombolytic infusion is in patients with massive PE. These patients are also good candidates for catheter-based thrombectomy or thrombolysis. Currently, our main percutaneous options are aspiration thrombectomy with or without intraclot administration of lytic drugs. In our practice, we have extended the indication for intervention to submassive PE as well. There is an ongoing European registry studying the efficacy of the EkoSonic catheter system (Ekos Corporation, Bothell, WA) for accelerated lysis of patients with PE, but the problem (or the opportunity) here is that the PE space is a very device-deficient arena and is badly in need of innovative technologies. ■

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CONTRAINDICATIONS: None known.
PRECAUTIONS: The Sterling ES OTW and Monorail PTA Balloon Dilatation Catheter shall only be used by physicians trained in the performance of percutaneous transluminal angioplasty.
CAUTION: Short-term and long-term biological effects at pressures above the nominal pressure are not known.
ADVERSE EVENTS: The complications that may result from a balloon dilatation procedure include, but are not limited to: Abrupt closure • Allergic reaction (device, contrast medium and medications) • Amputation • Aneurysm • Angina • Arrhythmias, including ventricular fibrillation • Arteriovenous fistula • Coma • Death • Deep vein thrombosis • Embolization air, device, plaque, etc. • Hematoma • Hemorrhage, including bleeding at puncture site • Hypotension/hypertension • Infection, local or systemic • Ischemia, including tissue ischemia, steal syndrome and necrosis • Myocardial ischemia or infarction • Need for additional intervention or surgery • Neuropathies or nerve injury • Organ failure (single, multiple) • Pulmonary embolus • Pain • Pseudoaneurysm • Renal failure • Restenosis • Shock • Stroke • Vessel injury, e.g., dissection, perforation, other claudication • Vessel occlusion • Vessel spasm • Vessel thrombosis • Weakness.

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