What is the most positive trend in the current office-based lab (OBL) landscape?

Currently, the most positive trend in the office-based angiosuite is the expansion of procedures being performed. Five years ago, I don’t think anyone would have pictured the breadth of cases we are doing now. The expansion of procedures performed in the OBLs is interesting in many ways. It requires interventionists to take on a more diverse case load as well as a more diverse patient population. As we take on a more diverse patient population, we need additional equipment, additional staff with more advanced training, and a workflow with protocols that allow us to care for an increasingly sicker population. Performing procedures that historically are considered more complex requires us to refine procedural techniques to make them economically feasible in the OBL setting. The drive to treat sicker patients with more complex disease in a safe and more economical fashion seems to be in perfect alignment with the overall goals of medicine. The best part about doing it in this type of facility is that the physicians are in control of how they make these changes. In my humble opinion, the single most positive trend in today’s atmosphere of managed care is that physicians are in direct control of improving how medical care is delivered.

What is the biggest challenge or issue that needs to be worked out?

The biggest challenge on the horizon for the OBL is the need for regulations that encourage safety but do not stifle the physicians’ ability to innovate. All OBLs are not designed the same way, and all physicians do not practice the same way. We need some regulations to ensure that there is a standard of quality that is being met by all OBLs as well as the physicians who practice in those facilities. However, those regulations need to allow for some flexibility for the physicians and facilities to change and adopt techniques and treatment plans to both improve quality and reduce costs appropriately. There are many physician specialties, professional societies, insurance carriers, and government regulatory bodies that have an interest in contributing to these regulations. Obviously, some will be in favor of stricter regulations on both the facilities and the physicians. I hope they consider that, just as in many other industries, allowing for innovation will help produce a better product, and in medicine, that means better outcomes at a reduced cost.

As someone specializing in deep venous therapy, which patients remain the most perplexing when it comes to therapeutic decision making?

When I approach any deep venous intervention, I break the procedure down into two parts: the thrombus management component and the secondary intervention. If the patient has an acute deep vein thrombosis (DVT), thrombus management will be a greater portion of the procedure than the secondary intervention. If the patient has chronic scarring or occlusion of their deep venous system, there will be little thrombus to manage and a significant amount of secondary interventions being performed. The treatment decisions that are most difficult for me are those for patients with thrombus between 4 and 8 weeks old. If the thrombus is < 4 weeks old, the decision is easy—you treat the patient provided there are no absolute contraindications. If the thrombus is older than 2 months, the decision is also easy—you complete the course of anticoagulation, and if the leg is still swollen, you perform venography to correct chronic venous scarring or occlusion.

For me, the hardest decision to make is when it is between the 4- and 8-week time period because the thrombus is much tougher to lyse or extract compared (Continued on page 88)
to typical acute thrombus, but has not contracted and scarred down to something that is easily fixed with angioplasty and/or stenting. This is typically the most difficult decision for me to make because I want to give the patient the best results with the least amount of complications.

You have designed and patented a stent concept. What are the novel elements or applications of the design, and how did the concept come to you?

I helped design and construct a prototype stent in my youth 20 years ago. It was a helical design constructed of nitinol coated with polyester with heparin bonding. It was functionally adjustable in situ from 3 to 26 mm and was designed for temporary use, as it was retrievable. Its initial intended use was to decompress the right heart by holding the tricuspid and pulmonic valves open during percutaneous bypass to allow for extended extracorporeal membrane oxygenation treatments. It had multiple other applications, but this is what the clinical trials were based on.

I went to a science and technology high school, and two engineers from the United States Naval Ordnance Laboratory gave us a demonstration on different material technologies. It was then that I was first introduced to shape memory alloys, specifically nitinol. I became interested in the properties of shape memory alloys not for their martensitic transformational properties, although that is pretty cool, but rather for their superelastic properties.

Through collaboration between my high school and various research facilities in the Washington, DC, area, I was lucky enough to have connected with Dr. Theodor Kolobow at the National Institutes of Health. He gave me a project to design a device that could hold open the tricuspid and pulmonic valves during percutaneous bypass to prevent overdystension of the right heart during prolonged percutaneous bypass. He was a phenomenal mentor who was instrumental in shaping the way I think about and approach technical challenges and problems. He provided guidance when needed, but also gave me the freedom to learn and innovate. Let’s just say he allowed me to reinvent just enough wheels for me to learn the concepts that I needed for future applications. Through a great mentor-student collaboration, as well as a machine shop and plastics lab, the device was designed, prototyped, and bench tested through multiple iterations and finally tested in animal models.

Can you tell us about the DVT and pulmonary embolism (PE) database you created and the metrics you deemed necessary in order to track outcomes and improve practice?

When I first started in practice, I went back to the community where I grew up. I was in a community hospital in private practice. For various reasons, I started treating acute DVTs and PEs. In the community I was practicing in, no PEs were being treated with interventional techniques, and DVT treatment was infrequent. When I first started treating PEs, I initially questioned whether I should be treating PEs in a community hospital with limited resources. In my mind, the ultimate metric is whether you are reducing the mortality rate of massive and submassive PEs as compared to treatment with anticoagulation and whether the mortality and complication rates are similar to or better than other facilities performing the procedure. I believed that, first and foremost, I needed to prove to myself that I was helping this patient population and secondarily prove to others that interventional treatment of massive and submassive PEs provided better outcomes than anticoagulation alone. That is why I constructed and maintained this database.

My goals with this database were to track the outcomes of the procedures performed to provide an objective evaluation of the results of these procedures. This is done in an effort to ensure quality and at least equivalent care when provided in the community setting. To that end, the database tracks demographic information; the diagnostic modality of the PE; if the patient had concurrent DVT, it documents the vital signs of those who are classified as having massive PEs; the echocardiogram results of patients who were classified as having submassive PEs; and details of the procedure, including the amount of lytics used, devices used, and duration of procedure. It documents the postprocedural hospital stay including length of stay, laboratory values, and anticoagulation regimen used during the hospital stay and upon discharge. The database also documents the results of the echocardiography that all patients undergo at 1 month, the duration of outpatient anticoagulation, hypercoagulable state if tested, and any complications or deaths.

When it comes to deep venous care, what is the limit of what can or should be offered in the office-based setting, in your opinion?

In the office-based setting, there is really no limitation on the procedures that can be offered from a technical standpoint. What really limits what should be
offered in this setting is the clinical situation and patient comorbidities. First, there are certain conditions that are rarely treated in the office-based setting due to the common presentation of illness. For example, it would be very rare for a patient with a massive or sub-massive PE to be referred to the office as opposed to being sent to the emergency department due to this clinical presentation, which is very appropriate. However, it would be quite common for a patient who has a 1-week history of arm or leg swelling to be referred to a physician’s office. So, there will be greater opportunities to treat an iliofemoral DVT or an occluded inferior vena cava filter in the OBL.

There are also certain clinical situations that would limit treatment in the OBL. For example, if a patient were at high risk for needing a blood transfusion, for any number of reasons, or if the patient might require additional observation after the procedure, such as a very elderly patient with dementia, this would limit the options for OBL treatment. The technical aspect of the treatments performed in OBLs will be continuously refined to increase the efficiency and safety to allow for treatment in this setting. However, patient factors and clinical situations are not affected by technical innovations.

**How can smaller community hospitals build expertise and a protocol system to provide safe and effective care for massive and submassive PEs?**

Absolutely, I think it is possible for smaller community hospitals to build expertise and a system to provide safe and effective care for massive and submassive PEs. I personally benefited from the fact that the hospital where I work treats ST-segment elevation myocardial infarctions, as there was already a system in place to bring in nurses and radiologic technicians to perform cardiac catheterization on an emergency basis. However, even with the cath lab having the system to function on an emergency basis at all times, this was only one part of the equation. The emergency physicians, the intensivist, and the hospitalist had to be educated on what types of PE could be treated. The cardiologists needed to be engaged to perform urgent echocardiography. The cath lab staff had to be comfortable with the thrombectomy devices, preparation of lytics, and dealing with arrhythmias and hypotension during the procedure. The intensive care unit and progressive care unit needed to be educated in terms of the aftercare for these patients. It also goes without saying that you need a physician (and preferably more than one) who is interested in performing these procedures.

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