Device Decisions for Office-Based Endovascular Labs

Key considerations in selecting everything from imaging equipment to disposables.

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The performance of minimally invasive endovascular treatments for peripheral arterial and venous disease in an office setting was, for me, the next logical step in the evolution of therapy for these widespread diseases. Current technology allows access to the vascular system and delivery of therapy through a single needle puncture (Figure 1). Patients who are treated in a hospital setting are observed for several hours postprocedure and then discharged to their homes in most cases. The level of anesthetic support and monitoring for these procedures has been safely used by other specialties in office settings for years, with minimal complications. Today's generation of radiological imaging equipment can rival or in some instances exceed what is available in hospitals. There is less exposure to hospital-based infections and a potential for overall cost savings to the health care system by eliminating the hospital charge for this service. In my opinion, physicians receive more equitable reimbursement for the work performed and practice costs incurred providing this service.

However, to achieve the optimal potential of patient outcomes that are similar to or better than those seen in hospitals and also maintain a viable vascular business model, the office-based endovascular lab (OBEL) must be properly designed and outfitted. This article addresses key considerations based on this vascular surgeon's experience.

ROOM DESIGN

Whether being added on to an existing office or designed for new construction, careful consideration and design of the overall floor plan is the critical first step in this process. Obtaining adequate space for equipment and storage with required radiation shielding and lighting is essential. The initial design must encompass the overall scope of procedures to be provided and equipment required to support each type of procedure offered.

Figure 1. A patient is prepped in the OBEL for vascular intervention.

A procedure room of at least 320 square feet should be considered; larger is of course better. The procedure room must sufficiently house all imaging equipment and storage for supplies, implants, etc., and there must be space for anesthesia equipment, monitors, and oxygen supply. Various states have specific regulations regarding radiation shielding for x-ray equipment, and these must be researched and taken into consideration. Adequate ceiling height is important for the accommodation of overhead-mounted monitor booms, and ceiling-mounted lighting design must be coordinated with ventilation

ducting. A sealed vinyl floor is desirable to maintain sanitary conditions and contain spills. Preprocedure and recovery areas should be in close proximity to provide smooth patient flow.

IMAGING EQUIPMENT

The heart and soul of the OBEL is fluoroscopic imaging equipment. Both fixed-base and mobile C-arm configurations can be applied. Budgetary constraints, procedural volume, number of users, and available space will weigh into this decision. Most interventionists have interacted with both types of systems. Arguably, the image quality generated from fixed systems is superior secondary to a larger image intensifier and software configurations. Postprocessing of images may be more sophisticated. However, the price of these units can approach twice that of mobile C-arm units. My personal experience is with C-arm use in this setting.

There are several mobile systems available, and these can either be purchased or leased. Significant consideration must be given to the imaging system decision. The unit chosen must provide images of high enough quality to yield sufficient anatomic detail of the target lesion. In my experience, an image intensifier of at least 12 inches is essential to view a large enough anatomic field to alleviate the need to constantly move the unit. The unit must perform digital subtraction angiography, with an acquisition rate of at least 15 frames per second. Road mapping functionality is essential. A bolus chase angiogram function allows visualization of a large field for intervention planning. The ability to collimate your imaging field will decrease radiation exposure to the operator and patient. The unit must perform quantitative angiography for precise vessel diameter calibration. The C-arm will ideally be motor-driven to provide orthogonal views when needed. Otherwise, if manually manipulated, its range of motion should allow full 90º travel. Retrieval of images and postprocessing should be intuitive, quick, and easy. An ideal system is completely controllable by the operator at the procedure table, with fingertip control of all functions. A configuration such as this is extremely efficient and may eliminate the need for additional personnel to manipulate the system.

All C-arm units are coupled to a mobile workstation where images are displayed and interactions with the system occur. The operator may lose visualization of his images each time the tech is asked to modify the function used. Therefore, additional independent "slave" monitors are invaluable. Whether suspended from ceiling mounts or floor-mounted booms, these will immeasurably improve the efficiency and visualization of the operator. Compatibility between the chosen monitors and the imaging system will need verification prior to installation.

IMAGING TABLE

The imaging table is the second most important component of any angiographic imaging system. Again, careful deliberation should take place prior to purchase or lease of this piece of equipment. The table should be designed solely for angiographic procedures and be constructed of carbon fiber with minimal metallic components in and around the imaging field. A catheter tray attachment for the foot of the table is valuable. Attachable arm boards and a headrest will provide maximum functionality. If hemodialysis access interventions are in the planned procedure offering, then an arm imaging extension without metal in the field is necessary. High-quality tables should have minimal radiation scatter to decrease patient and operator exposure.

The most important property of the imaging table is its ability to allow the operator to pan from head to toe. The length of available travel will decrease the need to move the C-arm during the course of the procedure. The panning function should be near effortless, with just fingertip control activated by an attached bedside "mushroom" control knob. Height adjustment, side roll, and Trendelenburg positioning should be available to the operator via pushbutton controls.

DISPOSABLES

The variety of available guidewires, catheters, sheaths, angioplasty balloons, self-expanding and balloon-expandable stents, and specialty devices is vast. The need to have many of these devices available in a variety of sizes and configurations further complicates maintaining an ideal supply. Specialty interventional modalities such as atherectomy devices, intra-arterial lasers, crossing devices, and clot lysis systems also often have individual control modules and protocols for their use. And, at the completion of the procedure, there is the access site to deal with and a decision as to whether to use a closure device, and if so, which one. All procedures require iodinated x-ray contrast material, which must be of adequate quality to provide usable images.

The best approach to sorting out this rather large and at times confusing landscape is to decide exactly which procedures you plan to offer and "build out" for each one. Each operator has developed individual preferences for wires, catheters, balloons, stents, etc., over the course of his or her career. One should review that preference list and attempt to duplicate its contents as closely as possible to provide that "comfort level" needed with such a new venture. One company may have the capability of providing a good percentage of the total materials needed; however, no individual company has everything. Therefore, proactively seek

out the sales reps who supply your preferred devices in your region. Discussions with these vendors should be friendly and easy. They are aware of the growing number of OBELs and are anxious to maintain and grow their market share in this demographic. Many companies can provide you with a "run list" of the basic wires, balloons, and stents that will be commonly used. It is easy to evaluate prices for comparable items between vendors and negotiate. Note, however, that these are relatively low-cost items, and it is better to work with what is comfortable instead of struggling with a new product just to save a few dollars. Guidewires, sheaths, catheters, and dye will not be consigned and must be purchased outright.

Contrast dye should not be overlooked, as this is essential to the quality of imaging studies. All agents are iodinated. Prices vary among producers of these agents based on concentration and whether they are iso-osmotic. It is worth investing in a quality agent that will provide crisp images without inducing sensations of heat or pain in the patient's leg.

Angioplasty balloons, stents, atherectomy devices, and others can and should be consigned. A list of appropriate sizes and lengths can often be recommended by the vendor and delivered at no charge. Mechanical control consoles, such as those required for atherectomy, should be provided at no charge by that individual vendor. Replacement of each used device will trigger a charge. This concept allows placement of a full complement of devices in the lab without need for expensive up-front payments. Next-day delivery of ordered devices is standard, usually with free shipping. Therefore, maintaining inventory is not difficult, but someone will need to perform this task diligently. Unlike the hospital setting, it won't just happen.

PROCEDURE PACKS AND INSTRUMENTS

Packs containing sterile angiographic drapes, sterile gowns, syringes for contrast, local anesthetic, heparinized saline, bowls for solutions, and wires, etc., are readily available from multiple sources. These can be custom built to your individual specifications at a surprisingly low cost. Additional disposable instruments such as scalpels and hemostats can be added to the pack to avoid the expense and maintenance of an autoclave.

ULTRASOUND

Many operators are accustomed to routinely performing ultrasound-guided access to the arterial system. One may question the value of this added technology for traditional retrograde femoral access. However, for antegrade femoral access, ultrasound may be useful, and it is almost essential for distal tibial retrograde access and SAFARI-type procedures. There are many types of ultrasound units available for access purposes, with various levels of sophistication and corresponding prices. Small, portable, laptop-type units with good-quality B-mode imaging and color Doppler capabilities will serve this purpose well. In addition to the usual vascular probes, a small-profile "hockey stick" is valuable for visualizing distal or small-caliber vessels for access. Another alternative is to use the workhorse unit from your vascular lab when the occasion arises, which is our current practice.

PACS

Storage and retrieval of completed studies is another issue to consider. The hard drive on the imaging system will accumulate images until full and then begin to "dump" the oldest data first. Obviously, this is not a permanent solution. On-site storage is a more costly option, which most likely will require a large-capacity server and appropriate software. Depending on the size and volume of the practice, this option may have merit. There are also multiple internet-based PACS storage vendors that are very reasonably priced. These services either charge per study or a flat rate per month. They guarantee HIPAA compliance, multiple backups, and 24-hour-a-day access through a secure internet portal.

CONCLUSION

The development and construction of an OBEL may appear to be a daunting task with so many factors to consider that a physician feels it is nearly impossible to achieve the potential this setting has to offer. True, the task may be long and arduous, but when completed, it might be the most satisfying accomplishment of one's career. Use of a competent and trustworthy consultant can certainly speed the process. A well-designed and efficiently functioning OBEL will add needed revenue to any vascular practice. In addition, there is the elimination of the stresses that accompany performing procedures in a hospital setting, and the pride and satisfaction of once again being in total control of what services you deliver to your patients. I firmly believe that in the future, the majority of endovascular surgical procedures will be performed in OBELs. ■

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