

PRACTICE MANAGEMENT

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Setting up an imaging center, adding computed tomographic, magnetic resonance, and an angiography suite to vascular labs

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Computed tomographic angiography (CTA), magnetic resonance angiography (MRA), and diagnostic arteriography are all vascular diagnostic tools that may be included in modern vascular diagnostic laboratories. Before undertaking the establishment of such an all-purpose diagnostic, and possibly interventional, facility the vascular specialist or group needs to ensure safe patient care and the ability to provide these diagnostic tests and procedures without incurring a financial loss. This article will detail one method of setting up such a facility and suggest some other approaches. It will also introduce some of the issues that may change the legislative landscape in the United States of America (USA) and may make these arrangements more complex in that country. (*J Vasc Surg* 2009;49:1073-6.)

The basic format of vascular surgeon-run vascular laboratories has remained essentially stable almost since inception. That is, labs utilize current noninvasive technology and avoid the use of any invasive procedure or the administration of any pharmaceutical agents for testing. Thus, computed tomographic angiography (CTA) and magnetic resonance angiography (MRA) have been excluded even though they can appropriately be considered vascular diagnostic modalities. Similarly, although diagnostic angiography is just another tool in the vascular surgeons' diagnostic armamentarium, it too has not been incorporated into the vascular "lab". This is despite the fact that over the last few years, clinical experience has proven that diagnostic arteriography as well as many endovascular interventions can be safely performed as an outpatient.¹⁻¹⁰

There are probably numerous reasons why vascular surgeons ignored these modalities and left them up to other specialists, notably radiologists and increasingly, cardiologists. The two dominant reasons are perhaps the extreme cost of setting up such a "full-service" facility and also inexperience with the technology. Further, most vascular surgeons have not followed some of the entrepreneurial trends demonstrated by general surgeons and gastroenterologists who have established outpatient surgery and endoscopy centers. However, incorporating these techniques makes for good economic sense for the vascular specialist. Furthermore, it should result in more efficient and improved diagnostic accuracy and hence better patient care.

This article will detail one method of setting up such a facility and suggest some other approaches. It will also introduce some of the issues that may change the political and legislative landscape in the United States of America (USA) and may make these arrangements more complex in that country. Since the author is not versed in legislation in other countries, all references to legal issues discussed in this manuscript will refer only to those that exist in the USA.

However, before embarking on establishing such a center, the surgeon/practice has to make a careful and detailed evaluation of the following issues since not all practices will be able to make a clinical or financial success of the venture.

ISSUES TO BE ADDRESSED

Is it safe? The patient's well being is paramount and therefore before establishing an outpatient center, safety concerns have to be evaluated. Certainly CT and MR have already moved into the outpatient arena and the safety of this approach is taken for granted. However, it was only in 2007 that Medicare and Center for Medicare Services (CMS) acknowledged that peripheral angiography and angioplasty could be performed in stand alone facilities. This decision was based on cost savings, (the average postprocedural cost for patients undergoing same-day discharge in one series was \$320 per patient, which contrasts with \$1800 for routine overnight observation⁷), as well as numerous manuscripts detailing the safety, not necessarily of such centers, but rather outpatient or same-day discharge hospital based angiography suites.¹⁻⁸ Gradinscak et al¹ collected data prospectively for 2683 procedures performed on an outpatient basis in 2248 patients from the period March 1997 to March 2002. Patients were assessed by nursing or medical staff within 2 to 4 hours of the procedure and again via telephone 24 to 48 hours after the procedure

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Table. Endovascular procedures performed in our facility over the last 18 months

<i>Procedure</i>	<i>Number</i>
Peripheral/cerebral/renal angiography	586
Angioplasty	242
Stents	117
Fistulogram	105
Total	1050

cedure. The collected data were summarized on the basis of procedure type into four main groupings: aortofemoral studies, cerebral studies, interventional procedures, and other studies. In total, 561 complications were identified in 2436 cases (23%), but most complications consisted only of either local pain or puncture site hematoma and bruising. No deaths occurred and there was a low incidence of complications requiring further treatment or resulting in a permanent deficit.¹ Zayed et al² showed similar good results even in diabetics and this was confirmed by Huang et al³ who also demonstrated the safety of outpatient angiography and vascular interventions in a radiology nurse-led specialist unit. Similar results have been reported even for a series where most procedures were performed using 6F catheters and where manual compression was used with discharge after just 3 hours.⁴ In that series, 183 elective day-case peripheral interventions were performed over 2 years. Five patients (2%) returned to the department because of persistent groin symptoms the next day. One of these had a false aneurysm. Four required no further treatment. A single patient returned at day 6 with a delayed false aneurysm. The rarity of major complications requiring operative intervention is evidenced by a study of 24,033 cardiovascular radiologic procedures performed at the Bristol Royal Infirmary where only 0.25% of procedures ultimately required surgical correction.⁵ That study was printed in 1999 and summarized 13 years of experience that must have included data from periods where catheters were larger and techniques were not necessarily as safe as currently utilized. Further, recent advances in balloons, stents, and stent grafts will now allow many complications to be immediately rectified in the angiography suite. Also, femoral pseudoaneurysms can also be safely treated in an outpatient setting with duplex ultrasound guided thrombin injection.

A survey of interventional radiologists' anesthesia practices demonstrated that the majority of procedures (56%) were performed at the awake/alert level of sedation whereas 32% were performed at the drowsy/arousable level and only 12% at deeper levels of sedation.⁶ Accordingly, precedent suggests that minimal sedation can be used in most cases such that anesthesia personnel should not be necessary. However, as will be seen later in this article, we have chosen to utilize anesthesia services although they usually administer only light sedation and then only at anxiolytic levels.

Even diagnostic cerebrovascular procedures can be safely performed as an outpatient. In one large study of 2924

diagnostic cerebral angiograms, clinical complications occurred in only 23 (0.79%) of the procedures: 12 (0.41%) significant puncture-site hematomas, 10 (0.34%) transient neurologic events, and 1 nonfatal reaction to contrast agent. There were no permanent neurologic complications.⁹

Based on the above evidence, most centers should be able to offer safe outpatient treatment. However, all involved must pay meticulous attention to all aspects of patient care including the ability to take care of medical emergencies such as cardiac arrhythmia, hyper/hypotension, and allergic reactions. Plans should also be in place for the rare situation where emergent admission to hospital is required. If safety can be guaranteed, the surgeon or practice can go on to consider the other issues that will need to be answered before setting up the lab.

EXPENSES

Space. This is the major stumbling block that most will encounter. A computed tomography (CT) machine requires at least 400 square feet and an MRA, 500 square feet. Patients also need changing rooms. Thus the size of a typical CTA suite is approximately 1000 square feet. Further, the rooms are expensive because of the requirement for lead walls. The size of a typical angiography suite is approximately 6000 square feet including the lab, six pre- and postprocedure patient beds, and areas for reception and administration. Certainly, this can be reduced if some of this space is shared with an existing outpatient office and vascular lab practice.

Equipment. The machines are also very expensive, although used machines or previous years' models can be readily purchased. Leasing the equipment may also be an alternative to reduce costs. Most manufacturers will also offer programs that guarantee that the machine will not become obsolete by offering buy-back and upgrade arrangements. However, to be competitive, currently at least a 64-slice CTA is required and a 1.4 Tesla magnet is probably a minimal requirement.

Disposables. This applies predominantly to the angiography suite where it is very easy to run up costs if the operator is not careful in selecting the appropriate catheters, balloons, and stents. A profligate physician can ruin the center financially. It will also help to meet with manufacturers to try to establish competitive prices for all purchases. In some instances, capitulated agreements can be entered into that will bundle costs for procedures. Since the beginning of 2008, Medicare is reimbursing stents, but insertion of more than one stent will result in a financial loss. Therefore, it is important, for example, in the superficial femoral artery (SFA) to use one long stent rather than two overlapping stents. This is also clinically appropriate. Technology such as re-entry catheters, atherectomy devices etc. may be too expensive to use in these outpatient centers since their use is currently not reimbursed.

Personnel. These tests are personnel intensive requiring radiology technologists as well as nurses. Our suite employs one full time and two part-time X-ray technologists. We also employ one full time in-room nurse and three

preop/postop nurses. In our center, we contract with an anesthesiology group to provide sedation for our angiographic and endovascular procedures. Although this is not essential, it has provided us with an added sense of security that we believe is well worth the extra expense.

Management and marketing. The addition of these modalities exponentially increases the requirement for someone in the practice to be actively involved in the lab's administration. Certainly, one of the practice physicians can take on that responsibility but this can be extremely time-consuming. Accordingly, in most labs, a fulltime administrator may be essential. This person can also be responsible for marketing the lab to other healthcare providers and the general public.

LOCATION

Space is also a major concern in that it has to be on-site with the vascular surgical practice; otherwise, it will fall afoul of current legislation, which governs independent diagnostic testing facilities (IDTFs). An alternative is for the practice to have a satellite office on location, but a practice physician has to be physically present during these tests. Further, the satellite must offer the full services of the practice and must be open at least 3 days a week. Accordingly, to satisfy these requirements some practices will be required to move their entire facility to a new building. As of this writing, angiography suites do not have to be at the same location as the practice (since they are currently not considered an IDTF). However, although currently exempt from this legislation, having the angiography suite in the same location as the primary practice allows for improved efficiency and safety, and it should be encouraged.

TEST/PROCEDURE VOLUME

Because of the expenses, a certain test volume will have to be reached in order to assure financial security. Accordingly, it is worth evaluating the last year's test/procedure usage to assure that there will be sufficient tests/procedures to at least break even on expenses. In doing this analysis, recall that Medicare and most insurance carriers have reduced payment for second body parts scanned in one sitting (e.g. abdomen and pelvis for abdominal aortic aneurysm [AAA]). Because of reductions in reimbursement for MRI/MRA and the very significant outlay required to incorporate these tests into the center, we would suggest that centers rather select CT/CTA and not purchase a MR machine. We have found that in the vast majority of patients, CTA provides all the necessary information. Further, the benefit of MRA in renal patients is no longer valid due to the problems with gadolinium and associated nephrogenic systemic fibrosis.

The break-even on a CT suite is at least six to seven studies a day, every day. However, a modern CT can evaluate the abdomen and pelvis in just a few minutes so there is room for many more tests, but it is unlikely that most vascular practices could legitimately generate this volume. Accordingly, the practice could offer to do nonvascular CT to the community, but this will necessitate hiring

a radiologist to read the studies. Further, this will require marketing and advertising which, in addition to the radiologist's fees, will significantly add to the expense of the studies. Since most cities in the USA have many competitive CT scanners, some of which are already finding it difficult to remain financially viable, such a relationship may make the addition of CT impractical. Further, various states may have regulations, which prohibit such arrangements. For example, the state of Florida, USA, currently prohibits a group practice from soliciting more than 15% of the total diagnostic test volume from sources outside the practice.

Break even on an angiography suite usually implies at least three diagnostic studies a day. This assumes that the suite incorporates a fixed overhead system and the pre- and postop areas outlined above. Naturally, use of portable X-ray units requires less space and up-front costs but image acquisition may not be optimal. Furthermore, we have found that use of portable units significantly adds to procedure time offsetting cost savings.

GO IT ALONE OR PARTNER

It is difficult for a vascular group of less than six partners to be able to generate sufficient volume to incorporate these expensive technologies unless they purchase/lease refurbished or older machines or, in the case of angiography, portable units. If a group cannot generate the volume on its own, then it would make sense to partner with another group even if it means merging to form one enterprise. This new partnership will need to establish a new unified billing number and will have to share expense and profit equally. Legislation prohibits reimbursement dependent on utilization.

For medico-legal reasons, it is probably appropriate to have a radiologist do over-reads on the CT and MR to avoid missing nonvascular pathology. Accordingly, a radiologist is a good partner for these centers especially if that individual can do nonvascular invasive interventions such as CT guided biopsies and endo-chemotherapy, thus, increasing the revenue generated by the angiography and CT suites.

LEASE ARRANGEMENTS

For those practices that cannot afford to set up the entire center on their own, lease arrangements can be made. However, these have to be at fair-market value and incorporate financial risk for the lessee. In other words, contracts have to be for at least 6 months and preferably a year and guarantee payment for a fixed number of tests/procedures or hours of use. Importantly, they also have to satisfy the location requirements outlined above.

NEW LEGISLATION

Can new laws change the picture? Unfortunately, the answer to this is a resounding – YES. Already CMS has proposed that leasing arrangements for CT/MR will be abolished or at least made so restrictive that most will not be legal, or if legal will not generate any chance of profit. However, CMS did place a moratorium on this issue for 1

year after a significant outcry from providers. Thus, the only safe method of establishing a center may be to own it outright (provided all the issues I have already outlined can be overcome). Another method that has been tried by some is to sell the practice to the hospital, thus, incorporating the outpatient center into the hospital budget. With the physicians as hospital employees some of the profit from these centers can be returned to the doctors as salary or bonuses.

Since angiography suites are not considered IDTFs, they are currently exempt from these restrictive legislative initiatives.

OUR MODEL

Our four vascular surgeon practice moved location into a new building, which we share with an oncology group (they are large volume users of CT, MR, and positron emission tomography [PET] scanners) and an IDTF that purchased the CT and MR. We have also made an arrangement with an interventional radiologist who built the angiography suite. He uses it for nonvascular invasive procedures. We do all the vascular procedures. We lease time on the CT and MR from the IDTF and employ the radiologist to read and report the studies. We also read the CTA portion but have the security that nonvascular conditions will not be overlooked. We lease space in the angiography suite from the same radiologist, but we do all the studies and reports unassisted and bill accordingly. Currently, we do all diagnostic studies including carotid arteriography in our center. We also perform all aorto-iliac interventions for nonaneurysmal disease and all infra-inguinal interventions except for thrombolysis and laser and mechanical atherectomy. Similarly, all dialysis related procedures are performed in the center including thrombolysis and catheter placement. Over the last 18 months, we have performed over 1000 studies (Table). Mechanical closure devices (StarClose®; Abbott Vascular, Redwood Calif) are seldom utilized or required but can expedite early discharge on busy days.^{10,11} The small expense incurred by use of a closure device is offset by the ability to increase turnover time and accordingly daily test volume. All except four procedures have been free of major complications. Two patients developed a retroperitoneal hematoma requiring transfer to a local hospital, and one patient suffered a non-fatal myocardial infarction on returning home. One patient developed a dissection unrelated to PTA, but this was well treated by a stent at the time of the procedure.

OTHER MODELS

If one has the capital and the entrepreneurship, perhaps the best method is to set up the entire center, hire a radiologist, and offer full service all-disease diagnostic services. If there is a powerful hospital chain, then selling the entire practice to the hospital will allow the practice to partner with the hospital in establishing the imaging center. Current regulations make this problematic unless the doctors are hospital employees. Although we think the following model may provides inferior quality of care, some

practices have purchased portable C-arm units, which require less space and do not require lead walls. Similarly, four-slice CT will allow passable tests and a machine and room can be constructed for less than \$500,000.

END NOTE

We have found incorporating CTA, MRA, and angiography to be very beneficial both financially and clinically. Our patients are also very appreciative because “one stop shopping” is very convenient. Further, they are well treated since we control all aspects of their care, test results are accurate, and workup is speedy and centralized outside of the “scary” hospital. We now perform at least 70% of all our work in the office, and this improves efficiency and quality of our lives. We hope that legislation will allow us to continue. We are extremely concerned that unscrupulous colleagues will ruin this for all of us by establishing similar centers where their only goal is the generation of income through abusive ordering of unnecessary tests or performing unnecessary procedures. However, currently we believe the addition of CT, angiography and, possibly, MR to our outpatient vascular lab has confirmed our position in the community as being the go-to vascular specialists.

REFERENCES

1. Gradinscak DJ, Young N, Jones Y, O'Neil D, Sindhusake D. Risks of outpatient angiography and interventional procedures: a prospective study. *AJR* 2004;183:377-81.
2. Zayed HA, Fassiadis N, Jones KG, Edmondson RD, Edmonds ME, Evans DR, et al. Day-case angioplasty in diabetic patients with critical ischemia. *Int Angiol* 2008;27:232-8.
3. Huang DY, Ong CM, Walters HL, Wilkins CJ, Evans DR, Edmondson RD, et al. Day-case diagnostic and interventional peripheral angiography: 10-year experience in a radiology specialist nurse-led unit. *Br J Radiol* 2008;81:537-44.
4. Kasthuri R, Karunaratne D, Andrew H, Sumner J, Chalmers N. Day-case peripheral angioplasty using nurse-led admission, discharge, and follow-up procedures: arterial closure devices are not necessary. *Clin Radiol* 2007;62:1202-5.
5. Lewis DR, Bullbulia RA, Murphy P, Jones AJ, Smith FC, Baird RN, et al. Vascular surgical intervention for complications of cardiovascular radiology: 13 years' experience in a single center. *Ann R Coll Surg Engl* 1999;81:23-6.
6. Haslam PJ, Yap B, Mueller PR, Lee MJ. Anesthesia practice and clinical trends in interventional radiology: a European survey. *Cardiovasc Intervent Radiol* 2000;23:256-61.
7. Akopian G, Katz SG. Peripheral angioplasty with same-day discharge in patients with intermittent claudication. *J Vasc Surg* 2006;44:115-8.
8. Kruse JR, Cragg AH. Safety of short stay observation after peripheral vascular intervention. *J Vasc Intervent Radiol* 2000;11:45-9.
9. Dawkins AA, Evans AL, Wattam J, Romanowski CA, Connolly DJ, Hodgson TJ, et al. Complications of cerebral angiography: a prospective analysis of 2924 consecutive procedures. *Neuroradiology* 2007;49:753-9.
10. Jaff MR, Hadley G, Hermiller JB, Simonton C, Hinohara T, Cannon L, et al. The safety and efficacy of the StarClose Vascular Closure System: the ultrasound substudy of the CLIP study. *Catheter Cardiovasc Intervent* 2006;68:684-9.
11. Wagner SC, Gonsalves CF, Eschelmann DJ, Sullivan KL, Bonn J. Complications of a percutaneous suture-mediated closure device versus manual compression for arteriotomy closure: a case-controlled study. *J Vasc Intervent Radiol* 2003;14:677-81.

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