VDM Vascular Disease Management

COMMENTARY

What Not To Do in an Office-Based Lab

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Introduction

With an increasingly aging population and a greater incidence of obesity and diabetes, the increase in prevalence of peripheral arterial disease (PAD) has been associated with a shift of endovascular procedures from the hospital to the outpatient setting.[1,2] Aside from favorable reimbursement rates, additional advantages include decreased costs, improved efficiency, excellent clinical outcomes, and greater patient satisfaction.[3] However, concerns surrounding patient safety and complications in the non-hospital setting remain.[4] No physician wishes to be the headline story because their patient died or suffered avoidable complications after an office procedure. Careful selection of which cases not to take is an effective way of avoiding such an event. Determining what cases to avoid in an office-based lab (OBL) is largely dependent on 4 major variables: the physician, the patient, the procedure, and the OBL itself. Although there are few absolute criteria, several general rules are relevant to each of these categories (**Table**).

Table. Considerations for Performing Procedures in an Office-Based Setting

Physician	• Appropriate licensing and credentials • Sufficient experience in procedure and managing complications • Operator is not in early residency or fellowship years
Patient	• Does not have unstable CAD, severe pulmonary disease or ASA of ≥4 • No limiting comorbidities: anxiety, dementia, severe spinal stenosis, morbid obesity • Accessible vascular access
Procedure	• Not overly complex • Will not require multiple procedures, anesthesia support or unavailable equipment • Reimbursable in the OBL setting
OBL	• Fully stocked with endovascular equipment and a crash cart • Well-trained personnel with endovascular experience • Written safety protocols and transfer agreement with local hospital

The Physician

The physician is a critical variable in determining which cases to avoid in an OBL. If the physician is not already credentialed in a hospital to do a procedure, they should generally not do it in the office setting. Credentialing, although imperfect, is at least an objective and externally reviewed evaluation of basic competency. The procedure should also not be done if the interventionalist is not already experienced in that specific procedure. The OBL is not the place for early learning, as there are limited resources compared to the hospital should complications arise. If one has only recently completed their residency or fellowship training, they should not independently start practice in an OBL; they need a mentor or senior partner to guide them through the inevitable learning phases. Finally, the OBL is not a place for teaching trainees early in their residency; only senior residents or fellows should perform parts of the actual procedures. The OBL needs to be highly efficient, and treating patients under local anesthesia places a time limit on the communication and instruction required for effective training.

The Patient

There are certain patients who should not have procedures performed in an OBL. Independent of the actual intervention, a patient's medical condition precludes such a consideration when they have unstable coronary artery disease and cannot be effectively monitored or treated should an arrythmia develop. Similarly, severe pulmonary disease that may require intubation or respiratory support that is not generally available in an OBL precludes procedures in that setting. These medical conditions are summarized with an American Society of Anesthesiologists physical status category of 4 or greater. Other exclusions would be an uncooperative patient due to dementia, psychiatric conditions such as anxiety, or disabling spinal stenosis that precludes them from lying supine for a sufficient period. The additional sedation that may be required in these circumstances, and diversion of the physician's attention from the procedure itself, represent additional disproportionate risks. Additionally, the morbidly obese patient (generally considered to weigh more than 157.5 kg) is more technically challenging and may be above the weight limits of the procedural table. Finally, one needs to always consider the relative difficulty of vascular access and the challenges of treating the underlying disease. A vascular cutdown or open vessel repair is not something generally done in an OBL, nor is a complex prolonged intervention that will take multiple hours.

The Procedure

Certain procedures should not be done in an OBL. Although some clinicians may contend that they can do any procedure in an office setting, the issue here is what can be done safely in the OBL, not the 10,000 cases done previously in a hospital setting. If the case is a patient who has already had multiple procedures and it is anticipated that the intervention will take several hours to complete, it should not be done in the OBL—it should be performed in a hospital or other facility where anesthesia support and other physicians are available to help and where there is an easy direct admission to an observation unit should complications arise. Although many OBLs are well stocked with catheters, stents, and bailout options, this is not always the case. If the procedure may require a stent or aspiration catheter that is not available, the procedure should not be performed in the OBL with the expectation that "it will probably work out." Planning a procedure should not be based on hoping that things work out but on having available options for most eventualities. There are still times when an open surgical procedure is better for the patient—this option should not be kept in reserve only as a last resort.

Finally, one should not do a procedure in the OBL if it is not reimbursable in that setting, such as iliac atherectomy or carotid stents, or when only a professional fee is paid, such as arteriovenous fistula creation. This puts the financial viability of the OBL in jeopardy and may possibly require an inordinately high financial payment from the patient.

The OBL

The OBL itself can be a limiting factor when deciding if a specific procedure can be safely done there. Although routine angiography and angioplasty can be performed with relatively few materials, an OBL needs to be fully stocked with a wide variety of endovascular tools of multiple sizes and lengths to deal with both routine and non-routine procedures, as well as their complications. One should not do procedures without sufficiently trained personnel who can easily start an IV, manipulate the C-arm, and understand what catheters or guidewires are needed when they are requested. Being a helpful nurse or a radiology technologist is not just having a degree, but also having the practical knowledge that can be applied in a variety of situations. A fully stocked crash cart with unexpired drugs, laryngoscope, and endotracheal tubes should always be available for the eventual patient who will have a cardiac arrest. Emergency protocols must be developed, written, and practiced by all staff. In addition, a written transfer agreement with a local hospital should be in place when patients need to be taken there.

Discussion

A review of the evidence supports the notion that a wide variety of procedures can be done in an OBL with minimal complications.[5] A retrospective review by Aurshina et al studied low- to moderate-risk venous and arterial interventions in a single OBL. They found no major complications within 72 hours of the procedure and a patient mortality of 0.3% at 1 month, which was deemed to be unrelated to the interventions. However, the vast majority (93%) of procedures in this study were venous ablations or iliac vein stenting, while only 3.9% accounted for arterial interventions.[6] A prospective study by Jain et al, in which 15% of total procedures were for PAD, found a complication rate of 0.8% and no deaths at 30 days.[7] However, of greater relevance are those studies that focus on the safety and efficacy of interventions for PAD. A study by Lin et al on office-based interventions included 5134 procedures, of which 51% were for PAD. The diagnostic angiography cohort had a complication rate of 3% while those undergoing intervention had a

complication rate of 1.5%. Mortality at 30 days was 0.2%, though none of these were procedure related.[8] A longer term, multicenter prospective study by Giannopoulos et al reported on outcomes of target vessel revascularization, major amputation, and death for patients undergoing intervention for PAD in an OBL. In a propensity-scored matched analysis, they found no statistically significant difference between the OBL and non-OBL settings at 3 years. Of note is that approximately one-third of the patients in both groups had chronic limb-threatening ischemia and 40% of the patients were graded at Rutherford 4 (rest pain) or 5 (tissue loss). Procedural success was very similar between the OBL and non-OBL groups at 82% and 84%, respectively.[9] The results of this study suggest that interventions for PAD can be conducted safely in the office-based setting and with favorable results. Such outcomes, however, reflect the results of experienced physicians in established OBL settings and careful patient selection.

Conclusions

Not every procedure should be performed in an OBL regardless of the skill of the interventionalist. The decision to carry out a procedure in an OBL vs a hospital setting is multifactorial and should be determined based on the physician, patient, procedure, and OBL characteristics. While the evidence supports the use of OBLs for peripheral vascular procedures, the most important factor is the individual patient. There are few absolutes in medicine, and sound clinical judgment is required to ensure patient safety and procedural efficacy in an OBL. ■

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REFERENCES

1. Fowkes FGR, Rudan D, Rudan I, et al. Comparison of global estimates of prevalence and risk factors for peripheral artery disease in 2000 and 2010: a systematic review and analysis. *Lancet*. 2013;382(9901):1329-1340. doi:10.1016/s0140-6736(13)61249-0

2. Jones WS, Mi X, Qualls LG, et al. Trends in settings for peripheral vascular intervention and the effect of changes in the outpatient prospective payment system. *J Am Coll Cardiol.* 2015;65(9):920-927. doi:10.1016/j.jacc.2014.12.048

3. Kennedy SA, Abraham RJ, Mujoomdar A, Valenti DA, Klass D, Wong JK. Interventional radiology in Canada: current challenges and future directions. *AJR Am J Roentgenol*. 2018;211(4):736-739. doi:10.2214/ajr.18.19996

4. Batchelor WB, Guzman E, Rodriguez CJ. Peripheral vascular interventions in office-based laboratories: good news for disparities or profit margins? *Circ Cardiovasc Qual Outcomes.* 2023;16(1): e009631. doi:10.1161/circoutcomes.122.009631

5. Mesbah Oskui P, Kloner RA, Burstein S, et al. The safety and efficacy of peripheral vascular procedures performed in the outpatient setting. *J Invasive Cardiol.* 2015;27(5):243-249.

6. Aurshina A, Ostrozhynskyy Y, Alsheekh A, et al. Safety of vascular interventions performed in an office-based laboratory in patients with low/moderate procedural risk. *J Vasc Surg.* 2021;73(4):1298-1303. doi:10.1016/j.jvs.2020.09.024

7. Jain K, Munn J, Rummel MC, Johnston D, Longton C. Office-based endovascular suite is safe for most procedures. *J Vasc Surg.* 2014;59(1):186-191. doi:10.1016/j.jvs.2013.07.008

8. Lin PH, Yang KH, Kollmeyer KR, et al. Treatment outcomes and lessons learned from 5134 cases of outpatient office-based endovascular procedures in a vascular surgical practice. *Vascular*. 2017;25(2):115-122. doi:10.1177/1708538116657506

9. Giannopoulos S, Pliagas G, Armstrong EJ. Procedural and 3-year outcomes of peripheral vascular interventions performed in office-based labs: LIBERTY 360 sub-analysis. *J Invasive Cardiol.* 2021;33(5):E365-E377.

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