

The Need for Accreditation of Office-Based Interventional Vascular Centers

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The rise in office-based interventional vascular laboratories in recent years was prompted in part by expedient ambulatory patient experience and favorable outpatient procedural reimbursement. While studies have shown that clinical safety and treatment efficacy can be achieved in office-based vascular facilities, critics have raised various concerns due to inconsistent patient care standards and lack of organizational oversight to ensure optimal patient outcome. Available literature showed widely varied clinical outcomes which were partly attributable to nonuniform standards in reporting clinical efficacy and adverse events. In this report, various concerns and pitfalls of office-based interventional vascular centers are discussed. Strategies to improve patient care delivery in office-based laboratories including accreditations which serve as external validation of processes to ensure patient care and safety are also mentioned. Finally, the requirements to obtain accreditation in an office-based practice and the differences between these nationally recognized accrediting organizations are discussed herein.

INTRODUCTION

Office-based surgery has emerged as an alternative to hospital-based and ambulatory surgery center (ASC) setting as a result of advances in anesthesia care, improvement in minimally invasive surgical techniques, and patient preference due to expedient perioperative experience. The shift of practice into the office-based setting offers some significant cost-effective solutions to surgical care, with one study reporting 60–75% reduction in healthcare cost.^{1,2} Many studies have demonstrated concurrent benefits of increased patient satisfaction and

expeditious patient experience.^{3,4} These factors have led to an exponential growth in office-based surgical practices, which is rapidly redefining how healthcare is being delivered. Several recent reports noted that the proportion of outpatient and office-based surgeries have increased from a meager 10–15% in the early 1990s to closer to 60% today.^{3,4} Many surgical operations which were traditionally performed as hospital-based procedures are now routinely being performed on an outpatient basis, with common examples including liposuction, reconstructive abdominoplasties, aesthetic breast reconstructions, orthopedic arthroscopic

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reconstructions, endoscopic spine procedures, and percutaneous endovascular procedures.⁵⁻⁷ The rapid expansion of these outpatient ambulatory surgical procedures in recent years have fueled the enthusiasm of office-based procedures among various surgical or interventional specialties, particularly in percutaneous catheter-based vascular interventions. While many vascular interventionists view this rapid growth of office-based laboratories (OBLs) as a merged evolution of advanced technology and expedient patient care, controversies and concerns regarding both patient care and regulatory guideline have been raised.^{5,8} This article examines these areas of concerns and discusses the role of accreditation as a step to improve healthcare delivery of office-based endovascular procedures.

PUBLIC HEALTH CONCERNS

As the Centers for Medicare & Medicaid Services modified reimbursement rates to encourage more efficient outpatient use of peripheral vascular intervention in 2008,⁹ many physicians have shown enthusiasm in outpatient vascular therapy as record numbers of OBLs have opened in recent years. This has resulted in a fundamental shift of practice pattern in that many endovascular peripheral interventions, which once were routinely performed in a hospital, are now being treated in an office setting. While supporters for this outpatient clinical practice highlight several perceived benefits including improved patient satisfaction and potentially less patient cost compared with hospital charges, many have raised concerns regarding potential public health safety and lack of unified standard of care in this healthcare delivery process. First, an OBL is a relatively isolated environment which carries the same potential risks that can accompany any surgical and/or anesthesia case. The isolated environment increases these risks as access to resources are more limited. Additionally, a private physician's office may not have the appropriate equipment, available resources, properly trained staff, or streamlined transfer policies in place should a medical or surgical emergency arise.

Another major concern from the public health perspective is the possibility of overuse or inappropriate care in office-based vascular interventions. Unlike procedures being performed in hospitals or ambulatory surgical centers, currently there is no consistent oversight for office-based endovascular procedures. There is also no established review process of treatment indications or outcomes following these interventions. Similarly, there is no required

licensing to assure the safety and qualities of these office-based endovascular interventions. To further complicate this matter, these percutaneous endovascular interventions can be performed by a diverse group of physicians from different specialties and training backgrounds, many of whom did not have formal endovascular training in their respective residency program.^{10,11} For instance, percutaneous interventions of visceral or lower extremity arterial disease are commonly performed by specialty physicians such as cardiologists, radiologists, or vascular surgeons. Endovascular treatment of dialysis-related access dysfunction is routinely conducted by nephrologists in their respective OBL setting. Ambulatory venous procedures can be similarly treated in an OBL by virtually any physicians regardless of their training or specialties. Undoubtedly, the lack of regulatory oversight can fuel a few physicians with unscrupulous intent to abuse this current healthcare system. This concern was echoed in a recent New York Times article in which it questioned the ethical conduct of a practitioner who performed high volumes of allegedly unnecessary peripheral arterial interventions.¹² The article speculated that higher office-based reimbursement may have played a motivational factor in this clinical practice.¹²

PHYSICIAN QUALITY IN ENDOVASCULAR INTERVENTIONS

The ability of individual physicians to practice medicine or perform surgery has traditionally been governed by board certification or licensure of their respective states. Physician licensure typically represents the basic legal requirement needed to practice medicine within a particular state, and currently there is no state-mandated competency requirement or qualification to perform endovascular arterial or venous interventions. In contrast, board certification is generally a voluntary process attained by individual physicians who have completed an approved residency or fellowship training program as well as passing their respective board certification examination. In most circumstances, board certification can be achieved by a physician shortly following the completion residency or fellowship training, and it generally does not require independent clinical experience or validation of clinical outcomes. Because board certification is generally voluntary and specialty defined, there is no unified consensus regarding specific clinical competency among different specialties in

Table I. Key studies addressing safety in office-based anesthesia

Key papers, year	Method	Finding
Hoefflin et al., 2001 ²⁰	23,000 cases from single plastic surgery office	No significant complications
Vila et al., 2003 ²¹	2 years of adverse events reported to Florida board	10-fold relative risk in office compared with ASC
Perrott et al., 2003 ²²	>34,000 oral and maxillofacial surgeries	Complication rate of 0.4–1.5% for all types of anesthesia
Byrd et al., 2003 ²³	5,316 cases from single plastic surgery office	Complication rate 0.7% (mostly hematoma)
Coldiron et al., 2008 ²⁴	Self-reported data to Florida board from 2000 to 2007	174 adverse events; 31 deaths in this time frame
Soltani et al., 2013 ²⁵	AAAASF data from 2000 to 2012; only reviewed plastic surgery offices	22,000 of 5.5 million cases; complication rate 0.4%, 94 deaths, 0.0017% death rate
Failey et al., 2013 ²⁶	2,611 cases from single AAAASF facility under TIVA/conscious sedation	No deaths, cardiac events, transfers; 1 DVT
Shapiro et al., 2014 ¹⁹	Comprehensive literature review	Improvements in patient outcomes likely with credentialing, accreditation, safety checklists, state and federal regulation, and national societies

DVT, deep vein thrombosis; TIVA, total intravenous anesthesia.

commonly treated diseases or therapeutic modalities, such as endovascular arterial and venous interventions.¹³

In some instances, board certification does not necessarily translate to quality or competent clinical skills in physicians, particularly when practitioners start a clinical practice.¹⁴ Undoubtedly, board certification was not designed to measure clinical quality or treatment outcomes provided by physicians. To address the issues of clinical competency, many medical specialties have recently imposed requirement for ongoing maintenance of certification for physicians.¹⁵ While this effort is praiseworthy, many physicians remain doubtful regarding the efficacy of maintenance of certification as it has not been shown to correlate with quality clinical outcomes.^{13–15} For therapeutic modality such as endovascular arterial or venous treatment whereby many physicians from various interventional subspecialties can provide similar care, there is a definite need to ensure quality of care for all involved parties, including insurance providers, government payers, and most importantly, our patients.

LACK OF REPORTING STANDARD IN OFFICE-BASED INTERVENTIONS

The rapid proliferation of office-based practices and surgical procedures performed outside of hospitals

has gained the attention of various professional societies and accreditation agencies in recent years, as these organizations have initiated an effort to implement a standardization of care for patient safety and quality of care provided in offices, ASCs, and hospitals.^{16–18} Despite this effort, clinical outcomes in office-based endovascular interventions remain widely varied as there is no uniformity in the reporting standard with regards to patient safety or adverse events in these office-based procedures. Shapiro et al.¹⁹ performed a comprehensive review and reported the safety data and treatment outcomes in office-based procedures with anesthesia support from 2001 to 2013. A brief summary of these studies is shown in Table I, which demonstrates varying results regarding the true risk of performing procedures in the office. This variation is due to nonuniformity in retrospective reports and puts into question the current safety standards which are being organized from these retrospective data.

There have been recent reports on the safety and efficacy of office-based surgery in various fields. In 2010, the Society for Ambulatory Anesthesia (SAMBA) focused on office-based safety outcomes based on data reported to the SAMBA Clinical Outcomes Registry. Of the 37,669 cases performed in the office, major complications comprised less than 1%.¹⁹ The American Society of Anesthesiologists (ASAs) has also begun collecting patient outcome data through a National Anesthesia Clinical Outcomes Registry (NACOR). NACOR also reported

only 17 adverse office-based anesthesia outcomes from over 300 participating facilities in various specialties since 2010 to date.¹⁹ For endovascular surgery, Jain et al.¹⁰ reported a 0.8% complication rate out of 6,458 percutaneous procedures done in the office setting in 2014. Ahn et al. also reported outcomes from over 3,100 cases in 2 centers over 4 years. Their complication rate was 1.29% and 30-day mortality was 0.09%, leading the authors to conclude that endovascular surgeries in office-based centers are safe.²⁷ Finally, a recent study reported 1.7% complication rate in arteriovenous fistula procedures and 1.35% complication rate in peripheral procedures out of 500 total procedures, with 90% success rate for the former and 82% success rate for the latter category.⁸ However, it is important to keep in mind that pervasive issues including a lack of uniformity in regards to state or federal regulations combined with voluntary reporting systems could result in understating the risk of procedures performed in the office.

IMPORTANCE OF ACCREDITATION

Rather than focusing on effort to standardize physician's licensure or board certification to ensure quality care, an important and powerful strategy to promote and evaluate the healthcare quality is through the process of accreditation.²⁸ This process recognizes that quality of healthcare is not uniquely dependent on the training and expertise of the physician, but also that of the entire clinical practice environment. In nearly all surgical cases, regardless whether office-based or hospital-based, patient outcomes are largely influenced by a wide range of many healthcare personnel, including operating room (OR) nurses, surgical assistants, OR technicians, anesthesiologists, recovery room nurses, and even housekeepers. Additionally, processes related to the clinical practice factors, such as surgical instrument preparation, maintenance of instrument sterility, radiation dosimetry monitoring, timeliness of patient scheduling and discharge, and safekeeping of analgesic and other pharmacological agents, play an equally important role in determining the quality of care.

New state mandates are requiring offices performing medical and surgical procedures to obtain accreditation. This is already required by nearly 30 states in the United States.^{17,25} Although such a mandate is not uniformly enforced in every state, there are clearly many benefits with obtaining accreditation in office-based practices. Accreditation introduces an objective third party to monitor,

validate the activities of an office-based practice, and provide a national acknowledgement of quality. This level of standardization provides confidence that the office-based surgery center has the same level of safety as that of ASCs or hospitals. Recognition in the healthcare industry among other office-based facilities is another compelling benefit to seek accreditation. Patients, insurance carriers, and even physicians employed by the office practice may have a better perception of a center with accreditation because the practice will have met a higher standard of care, or at least that equal to hospitals and ASCs. Thus, it may provide a competitive advantage over other office-based facilities that are not accredited. Finally, accreditation validates all aspects of an OBL: administrative, clinical, and surgical. The administrative points include facility and equipment maintenance, medical records documentation, and credentialing of personnel. Clinical considerations include patient rights management, approval of procedures in the office, and nursing services. Surgical issues include preoperative testing requirements, medication administration, and risk management.^{17,25}

Accreditation of an office-based interventional vascular center can benefit all parties involved, as long as proper safety measures and quality of care are upheld. Improved collection of outcomes with more prospective data and randomized controlled trials can provide statistically significant results on which to base new safety standards. The government has answered this need by providing financial incentives to participate in outcome registries. There are now a number of outcome registries including NACOR, American College of Surgeons National Surgical Quality Improvement Program (NSQIP) database, Medicare, and State Ambulatory Surgery and Services Databases.¹⁷ Reportable events in the ASA's Closed Claims database have prompted new measures targeted at avoiding these potential life-threatening complications in the office.¹⁷ Patient safety checklists specific to office-based practice have also been introduced as a further step to improve patient safety and outcomes.²⁹ These patient safety methods, in addition to diligent reporting of practice issues and adverse events, can also provide crucial information and help shape office-based safety not just in anesthesia but also in other practices including endovascular surgery.

ACCREDITATION ORGANIZATIONS

There are currently 3 major nationally recognized accrediting organizations: (1) the Accreditation

Association for Ambulatory Health Care (AAAHC), (2) The Joint Commission, and (3) the American Association for Accreditation of Ambulatory Surgery Facilities (AAAASF). Organizations seeking accreditation need to submit a written application and undergo periodic on-site surveys to assess compliance with published criteria. These 3 agencies all have similar requirements for accreditation, but there are some subtle differences. Overall, these accreditation agencies generally focus on structure and process variables. The main objectives of this process are to ensure that accredited organizations have an organizational structure and governance that provides proper oversight, sufficient facilities and equipment, appropriately trained providers, and established policies and procedures to ensure safe and high-quality patient care. More recently, these accreditation organizations are also seeking evidence of high-quality patient outcomes through requirements for benchmarking and ongoing quality improvement activities. All 3 accrediting agencies have programs for both office-based facilities as well as licensed ASCs; generally, the standards for accreditation do not differ significantly between the office-based or ambulatory surgical facilities.

The AAAHC was founded in 1979 with a focus on outpatient facilities and now accredits more than 6,300 organizations.^{28,30} This is one of the more popular agencies for accreditation and has even developed an accreditation handbook with guidelines designed specifically for office-based surgery. The accreditation handbook has been developed to assist organizations seeking accreditation in the review and application of the Standards for an office-based surgery practice with the intention of ensuring that the highest level of healthcare services is provided.³⁰

The Social Security program was established in 1965 which mandated that hospital accreditation by the Joint Commission on Accreditation of Hospitals was necessary for hospital participation in the Medicare and Medicaid programs.³¹ As a result, this accreditation became a *de facto* requirement for all hospitals. Since that time, the organization has expanded beyond hospital accreditation to include more than 20,500 healthcare organizations and programs in the United States.³² This organization, which was since renamed as the Joint Commission, also introduced standards and a survey process in 2001 for primary care, ASCs, and office-based surgery centers.^{32,33} The Joint Commission is currently providing accreditation for more than 400 office-based surgery practices.^{28,34,35}

The AAAASF, founded in 1980, provides accreditation for outpatient facilities, with the mission to

standardize and improve the quality of medical and surgical care while assuring high standards of patient care.³⁶ The AAAASF requires that all physicians be board-certified for that specialty to perform procedures, which could prove difficult given that not every provider is board-certified in the particular subspecialty in question. Unlike the AAAHC, AAAASF also requires that the facility performs a self-survey and provides yearly documentation. Currently, this organization has accredited more than 2,000 outpatient facilities.^{28,37}

Accreditation agencies maintain a set of guidelines or policies and procedures that are designed to aid in obtaining and maintaining accreditation. These guidelines and policies are written in great detail and should be tailored and customized to each office practice. Policies should be reviewed as issues arise, incident reporting should be utilized to prompt policy review and/or changes, and education of staff and providers is paramount to obtaining and sustaining accreditation. Current guidelines and policies with up-to-date standards can be easily accessed online from the respective accrediting organization.

Accreditation validates all aspects of office-based centers: administrative, clinical, and surgical. The administrative points addressed include facility and equipment maintenance, medical records documentation, and credentialing of personnel.^{16,17,38} Clinical considerations include patient rights management, approval of procedures in the office, and nursing services. Surgical issues include preoperative testing requirements, medication administration, and risk management. Quality improvement programs are another important objective of the accrediting organizations. Office-based practices are vulnerable to quality lapses and documenting quality improvement measures and adverse events are crucial to identifying and eliminating these vulnerabilities. They can include more mundane issues such as patient wait times, procedure room turnaround times, and complication rates.

The accreditation organizations perform an on-site survey when an office practice is being considered for accreditation. The visit consists of a brief 1-day visit, with the accrediting agency acting as a consultant to ensure that the practice is set up properly and “ready” for the survey. They will return at a later date for the full accreditation survey which typically occurs 6 months later; followed by subsequent visits every 1–3 years between surveys.²⁸ Between surveys, it is important to always get an update on accreditation standards each year. Performing periodic self-inspections within the office would be helpful to ensure compliance.

In addition to the aforementioned accreditation organizations, several professional society-based accreditation programs have also been established for more focused areas in cardiovascular systems. The American College of Cardiology has 6 programs in diagnostic and interventional cardiac and vascular procedures.³⁹ Similarly, the American College of Radiology has accreditation programs in 9 areas of imaging.⁴⁰ Other organizations have specifically been created to provide accreditation in areas such as chest pain and heart failure.⁴¹ Similar accreditation specifically for ambulatory or office-based venous centers was recently established.⁴²

CONCLUSION

Interventional procedures in the outpatient and office-based setting have exponentially grown in the last 2 decades with current trends suggesting continued rapid growth in the future. The growth volume and complexity of cases, in addition to patients with increased comorbidities, will continue to create challenges for office-based safety. Accreditation of an office-based interventional vascular center can benefit all parties involved, including physicians, insurance providers, and government payer, and ultimately patients. Proper safety measures and quality of care must be upheld to ensure optimal healthcare delivery and treatment outcome. Various accreditation organizations are designed to meet these healthcare objectives in office-based facilities. Taken altogether, multiple measures including facility accreditation, utilization of outcome registries, the use of patient safety checklists, and further involvement of state and federal agencies will serve as important building blocks for improved safety in the office-based and ambulatory settings.

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