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REVIEW

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Safety in Office-Based Laboratories and Ambulatory Surgery Centers

Krishna Jain, MD, FACS

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Key Summary

- The author conducted a narrative review of safety regulations and published outpatient literature covering office-based laboratories (OBLs) and ambulatory surgery centers (ASCs); no new randomized controlled trials or cohort were conducted.
- The review summarizes evidence that endovascular procedures in OBLs and ASCs achieve safety outcomes comparable to hospitals when standardized policies and compliance are in place; literature reviewed showed low transfers and zero procedure-related mortality across large outpatient procedures.
- Governance, written protocols, trained staff, ALARA radiation practices, mock drills, and registry participation are emphasized. Limits include narrative design and reliance on heterogeneous published data; continuous monitoring and appropriate patient selection are recommended.

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Introduction

The transition of surgical and interventional procedures from hospitals to outpatient settings has accelerated over the last 20 years. Office-based laboratories (OBLs) and ambulatory surgery centers (ASCs) now perform a significant proportion of vascular, orthopedic, gastrointestinal, and pain management procedures. A disproportionately high number of endovascular interventions are done in OBLs compared with ASCs. While OBLs provide a more flexible, physician-led environment for interventional procedures, ASCs are regulated under the Centers for Medicare and Medicaid Services (CMS) Conditions for Coverage, emphasizing comprehensive patient safety standards. Regardless of classification, both settings must adhere to rigorous clinical, technical, and administrative policies to ensure patient safety and compliance with federal, state, and accrediting body requirements.

Methods

A review of current safety regulations and standards was conducted using the CMS Conditions for Coverage (42 CFR §416),[1] Occupational Safety and Health Administration guidelines, and accreditation standards from the American Association for Accreditation of Ambulatory Surgery Facilities, Accreditation Association for Ambulatory Health Care, and The Joint Commission. Published literature related to safety in an outpatient setting was reviewed. Based on that, several areas were identified in patient care where patient and staff safety can be compromised.

Results

In providing safe care to patients, the areas where OBLs and ASCs need to concentrate include credentialing/competence, infection control, anesthesia safety, radiation safety, emergency preparedness, and continuous quality improvement.

Discussion

Endovascular procedures can be safely performed in OBLs, as shown in the **Table**.[2] There are more than 5000 ASCs in the United States; most have been providing care for patients with gastrointestinal, orthopedic, ophthalmologic, and plastic surgery-related conditions. Lately, cardiovascular ASCs are being developed as CMS moves away from inpatient-only procedures to a more liberal policy by which many cardiovascular interventions can be carried out in an ASC setting.[3] Many cardiovascular ASCs also provide care to patients with peripheral arterial disease. ASCs are much more regulated than OBLs; results published from ASCs[4] are comparable with results published from OBLs.

Table. Summary of results from 3 different office-based labs and Vascular Quality Initiative data.

Authors	Number of procedures	Complications	Transfers to hospital	30-day mortality	Procedure-related mortality
Jain et al[5]	6458	564	26	18	0
Lin et al[8]	5134	73	22	9	0
Mesbah Oskui et al[9]	500	7	1	Not reported	Not reported
Chow et al[4] (data from VQI)	4448	208	21	Not reported	Not reported
Totals	16540	852	70		

Abbreviation: VQI, Vascular Quality Initiative.

Safety in OBLs and ASCs is multifactorial, requiring an integrated approach across organizational, procedural, and human resources. Although OBLs may operate with less direct CMS oversight than ASCs, the expectation for equivalent safety outcomes is increasingly recognized by regulators, payers, and patients. Evidence suggests that outcomes in OBLs5 and ASCs[4] can match or exceed those in hospital settings when policies are standardized and compliance is monitored. Safety begins with written policies and procedures; each organization should have written policies and procedures related to various aspects of patient care that are followed diligently and updated as needed. Operators and staff should follow appropriate policies relevant to their job descriptions.

Credentialing and competence

Because the OBL is an extension of practice, the practicing physician would have the competence to do procedures in the OBL. Credentialing may be required if there are operators who are not part of the practice. In the ASC, there are usually many operators who need to be properly credentialed and competent. Nurses and other support staff should have appropriate training and be checked for competence for roles designed for them. For example, registered nurses should have Advanced Cardiovascular Life Support certification. Radiology technicians should have appropriate training to run the C-arm or the fixed x-ray machine. Guidelines are published by credentialing agencies and CMS that should be adhered to.

Emergency preparedness

When the site is built, it should follow the required rules and codes[7] so the patients and staff can be safely protected and evacuated in case of an emergency. Mock drills to replicate cardiac arrest and other natural disasters at should be conducted at least once yearly. Records should be maintained in case of an audit.

Continuous quality improvement

Monthly meetings should be held to look at results. The center should participate in national registries so the data can be compared at the local, regional, and national level. If the results do not match or exceed the results from the other centers, appropriate measures should be taken to improve quality and recheck the results. The process should include employees who are taking care of patients as well as support staff. For example, if a patient is not called in advance to be advised about medications that should or should not be taken prior to the procedure, the patient may come to the center and bleed postoperatively because an anticoagulant was not stopped in time. To improve quality, the person who was designated to call the patient should become part of the solution. Patient satisfaction surveys should be a standard part of the practice. Based on patients' feedback, processes can be improved to deliver safer, patient-friendly care. Remember that some patients may not be suitable to be treated in OBLs or ASCs. Higher-acuity patients may be best treated in the hospital.

Conclusion

Patient safety in OBLs and ASCs depends on structured governance, rigorous infection control, trained personnel, and active quality improvement systems. Establishing a culture of safety supported by data monitoring, accreditation, and continuous staff education ensures optimal outcomes and regulatory compliance. The whole organization should be safety and quality driven. ■

Affiliation and Disclosure

Krishna Jain, MD, FACS, is from Western Michigan University Homer Stryker MD School of Medicine in Kalamazoo, Michigan.

The author reports no financial relationships or conflicts of interest regarding the content herein.

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Address for correspondence: Krishna Jain, MD, FACS, Western Michigan University Homer Stryker MD School of Medicine. 300 Portage Street, Kalamazoo, MI 49007. Email: dockrishna1@gmail.com

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