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REVIEW

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Safety of Outpatient Endovascular Interventions for Peripheral Arterial Disease: Evidence and Applications for U.S. Practice

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Key Summary

- This review synthesized 31 studies (99,600 day case procedures; 2000-2024) plus U.S. registries and real-world cohorts evaluating outpatient peripheral endovascular intervention (PVI) for peripheral arterial disease.
- Meta-analysis showed 0.64% major complication rate (95% CI, 0.48%-0.79%) and 93% technical success (95% CI, 91%-96%); outpatient vs inpatient complication rates were not significantly different.
- Evidence supports outpatient PVI in appropriately selected patients; structured selection/access management are emphasized, while long-term patency and reintervention require further study.

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Abstract

Background: Peripheral arterial disease affects more than 200 million individuals worldwide and imposes a substantial burden on U.S. healthcare systems. Endovascular revascularization has become the dominant first-line strategy, and same-day outpatient delivery is increasingly recognized as safe, cost-effective, and scalable. **Methods and Materials:** This review synthesizes data from a 2024 landmark systematic review and meta-analysis encompassing 99,600 day case procedures across 31 studies, U.S.-specific Vascular Quality Initiative (VQI) registry data across 3 outpatient settings, real-world experience in rural and diabetic populations, high-volume U.S. office-based lab series, and emerging retrograde tibiopedal access data. **Results:** Pooled major complication rates were 0.64% and technical success reached 93%, with no significant difference vs inpatient treatment. VQI data from 66,101 U.S. cases confirmed safety across all outpatient settings, with hospital admissions below 0.70% regardless of site. In rural and diabetic populations, same-day discharge exceeded 99%. Access-site hematoma was the dominant complication across all datasets. **Conclusion:** Outpatient peripheral endovascular intervention is safe for appropriately selected U.S. patients across all practice settings. Optimal access-site management and structured patient selection are the critical determinants of safety. Long-term patency and reintervention data remain important areas for ongoing investigation.

Introduction

Peripheral arterial disease (PAD) is a leading cause of limb loss and a major driver of cardiovascular morbidity, affecting an estimated 200 million individuals globally with more than 8 million Americans living with the condition.[1] Chronic limb-threatening ischemia (CLTI) carries a 1-year risk of major amputation or death approaching 50%, making timely revascularization a clinical priority.

Endovascular intervention has displaced open surgical bypass as the predominant first-line approach across most U.S. centers, supported by the "endovascular first" strategy endorsed by the 2024 ACC/AHA PAD Guidelines.[2] As procedural volumes have grown, so too has the shift away from inpatient hospital settings toward outpatient venues. Between 2006 and 2011, peripheral vascular interventions (PVIs) in U.S. office-based labs (OBLs) increased from 6 to 37.8 per 100,000 Medicare beneficiaries.[3] More recently, OBLs have come to account for the majority of all PVIs among Medicare beneficiaries, with market share rising from 48.3% to 65.5% between 2017 and 2022.[4] This migration reflects expanded Centers for Medicare and Medicaid Services (CMS) reimbursement policies, patient preference for outpatient care, increased adoption of lower-profile access devices, and growing operator confidence in ambulatory safety profiles.

Despite this rapid expansion, robust comparative safety data have until recently been limited. This article reviews the current evidence, including a 2024 landmark meta-analysis, large U.S. registry data, high-volume OBL series, and real-world experience in rural and high-risk populations, to describe the safety, efficacy, and appropriate application of outpatient PVI in contemporary U.S. practice.

Safety Evidence: What The Data Show

The 2024 meta-analysis: global benchmark, U.S. relevance

Hanna and colleagues published a systematic review and meta-analysis providing the most comprehensive quantitative synthesis of outpatient endovascular safety data to date.[5] Across 31 observational studies and 1 randomized controlled trial —covering 99,600 outpatient lower-limb procedures in 93,344 patients from 2000 to 2024—the analysis included 16 U.S.-based studies, making its findings directly applicable to U.S. practice.

Minor complications occurred at a pooled incidence of 4.7% (95% confidence interval [CI] 3.8%–5.6%), with access-site hematoma or bruising accounting for the majority (1.6%). When studies reporting pain as a complication were excluded in sensitivity analysis, the pooled minor complication rate fell to 2.7%, underscoring that complications arise primarily from vascular access, not from the revascularization procedure itself.[5]

Major complications were uncommon at 0.64% (95% CI 0.48%-0.79%), well within the Society of Interventional Radiology acceptable thresholds for major vascular access complications (≤3%) and catheter-induced complications (≤1%).[6] Ischemia or vessel occlusion accounted for 0.28% of procedures, while major bleeding comprised 0.14%. Death was reported in only 0.0016% of cases. Technical success reached 93% (95% CI 91%-96%). Critically, in the 6 studies that directly compared outpatient vs inpatient outcomes, total complication rates did not differ significantly (pooled difference –0.8%, 95% CI –1.9% to 0.3%).[5]

Conversion to hospitalization occurred in 1.6% (95% CI 1.1%-2.2%) of outpatient procedures, and readmission after discharge was 0.11% (95% CI 0.095%-0.23%). Major complications arising after discharge and requiring readmission occurred in just 0.081% of cases.[5] This strongly suggests that when complications occur, they are predominantly detectable and manageable within the postoperative observation window.

U.S. registry data: Vascular Quality Initiative evidence and Outpatient Endovascular and Interventional Society National Registry across all outpatient settings

The most direct U.S.-specific evidence comes from a retrospective analysis of the Vascular Quality Initiative (VQI) database by Chow and colleagues, encompassing 66,101 elective infrainguinal PVIs performed between 2016 and 2021 across hospital outpatient departments (HOPDs) (83.3%), ambulatory surgical centers (ASCs) (6.95%), and OBLs (6.73%).[7] This is among the most robust databases, as it included multispecialty practices (interventional cardiology, interventional radiology, and vascular surgery) and academic institutions, teaching hospitals, and community practices.

Postprocedural hospital admission rates were low and did not differ significantly across settings: 0.70% for HOPDs, 0.57% for ASCs, and 0.47% for OBLs (*P*=.126). There were no significant differences in cardiac, pulmonary, or renal complications. Technical success exceeded 92% regardless of setting (**Table**).[7]

Table. Key safety outcomes by procedural setting[7]

Outcome	HOPD (n = 57,062)	ASC (n = 4591)	OBL (n = 4448)
Hospital admission	0.70%	0.57%	0.47%
Any access complication	1.61%	0.41%*	1.67%
Access hematoma	1.42%	0.33%*	1.53%
Cardiac complication	0.29%	0.15%	0.25%
Technical success	92.3%	94.3%	93.3%

**Significantly lower than HOPD and OBL on multivariate analysis (aOR 0.27, P<.001). Abbreviations: HOPD, hospital outpatient department; ASC, ambulatory surgical center; OBL, office-baed lab; aOR, adjusted odds ratio.*

Access-site complications occurred in fewer than 1.7% of cases across all settings, with ASCs demonstrating the lowest rates of access-site complication. Multivariate analysis suggested this was likely because there was greater use of ultrasound- and fluoroscopy-guided access in ASCs (96.8% in ASCs vs 87.9% in OBLs), lowest preprocedural anticoagulant use in ASCs, and highest periprocedural protamine administration.[7]

The Outpatient Endovascular and Interventional Society (OEIS) National Registry, established in 2017, has provided cumulative U.S. data on OBL safety, reporting an overall complication rate of 1.87%, major adverse event rate of 0.51%, hospital transfer rate of 0.62%, and 30-day mortality of 0.03% across more than 18,000 interventions.[8] These registry data are consistent with pooled estimates from the meta-analysis and VQI data, further supporting the generalizability of the safety of outpatient endovascular procedures.[5]

Large U.S. office-based lab series: High-volume real-world experience

Several large U.S. series add important real-world context. Lin and colleagues reported outcomes from 5134 consecutive outpatient procedures performed over 7 years at a vascular surgical OBL practice.[9] The analysis included 1568 arterial interventions and demonstrated a declining complication rate across sequential cohorts of 1000 procedures, from 3.0% in the first group to 0.7% in the fifth over time, reflecting a learning curve in outpatient endovascular care. The 30-day mortality rate was 0.18%, with no procedure-related deaths, and the hospital transfer rate was 0.29%.[9]

Malgor and colleagues evaluated 483 procedures at an academic OBL at a U.S. tertiary center, achieving an overall technical success rate of 97%.[10] Complications occurred in 10 patients (2.1%), with 4 of them being transferred to the emergency department with reasons including acute limb ischemia, arterial pseudoaneurysm, and cardiovascular events; there were no procedure-related deaths. All complications were found within the postoperative monitoring window. This academic experience demonstrates safety in a setting more reflective of the high-comorbidity patient population typical of university vascular surgery practices.[10]

A focused comparison of outpatient tibial artery interventions between OBL and hospital angiography suite settings was performed by D'Souza and colleagues, who reviewed 204 procedures in 161 patients.[11] Thirty-day local complication rates (7% vs 11%, *P*=.368), systemic complication rates (4% vs 8%, *P*=.263), and mortality (1% vs 2%, *P*=.596) did not differ significantly between OBL and hospital groups. Unplanned postprocedure hospital admissions were significantly lower in the OBL group (2% vs 11%, *P*=.01). Kaplan-Meier estimates at 1 year favored the OBL group for primary patency (69% vs 53%, *P*=.050).[11]

Longer-term outcomes are supported by the LIBERTY 360 sub-analysis by Giannopoulos and colleagues, which compared 355 propensity-matched OBL patients with 355 non-OBL patients followed for 36 months.[12] Risk of major amputation, death, and major adverse limb events did not differ significantly between settings at 3 years, supporting the durability of OBL-based endovascular outcomes beyond the perioperative period.[12]

Real-world evidence: Rural and diabetic populations in the United States

A retrospective analysis from a rural Southern California OBL—serving a predominantly Hispanic population with limited access to tertiary vascular services—evaluated 608 lower extremity arterial interventions performed between 2012 and 2015.[13] The major complication rate was 0.66%, and 99.34% of patients were discharged safely on the same day. No adverse events were reported at 30-day follow-up. These results are notable given that 31.6% of treated lesions were total occlusions and 63% to76% were classified as complex by lesion length, with case complexity rivaling that of many inpatient series.[13]

Similar findings were reported for diabetic outpatients with peripheral vascular disease. In a single-center study at a high-volume interventional radiology practice, 811 endovascular interventions were performed in an outpatient setting in diabetic patients with disease ranging from claudication to advanced CLTI.[14] The immediate technical success rate was 87%, and the 30-day hospital admission rate was 2.2%. Fewer than half of those admissions were attributable to procedural complications. These data support the feasibility and safety of outpatient PVI even in the high-comorbidity diabetic population that constitutes a substantial proportion of U.S. patients with PAD.[14]

Patient Selection: A Framework for U.S. Practice

Safety outcomes depend on appropriate patient selection. Across the 18 studies in the Hanna et al meta-analysis that reported formal eligibility criteria, a consistent exclusion criterion emerged based on sociodemographic, medical, and procedural factors.[5] The systematic review by Cook and colleagues, focused exclusively on U.S. publications, further clarified exclusion criteria across 14 OBL-specific studies.[15]

Sociodemographic criteria include the presence of a responsible adult companion overnight (cited in 94% of studies),[5] ability to stay within reasonable distance of a hospital, telephone availability, and adequate comprehension and cooperation with postprocedural instructions.

Medical criteria include stable coagulation status (no coagulopathy, international normalized ratio <1.5, platelets >75 × 109/L, no bridging anticoagulation), American Society of Anesthesiologists (ASA) class I to III without unstable cardiovascular comorbidity, and no severe renal impairment (estimated glomerular filtration rate [eGFR] >30 mL/min/1.73 m²). Severe chronic kidney disease warrants close monitoring given the risk of contrast-associated nephropathy, which typically presents 2 to 3 days post-exposure.[5,15]

Common exclusion criteria across U.S. OBL series include morbid obesity (weight exceeding 350-400 lb), ASA class IV or V, known contrast allergy, inability to lie flat, and cases deemed procedurally high-risk for the outpatient setting.[9,15] CLTI status alone was not a universal exclusion criterion in the reviewed literature. Multiple studies have demonstrated that tibial interventions and retrograde chronic total occlusion (CTO) revascularization can be performed safely on an outpatient basis when other eligibility criteria are met.[5,11,16]

Optimizing Access Site Safety

Given that access-site complications dominate the outpatient endovascular complication profile across all reviewed datasets, optimizing access site management is the single most modifiable factor in outpatient program safety.

Ultrasound-guided access reduces inadvertent arterial wall injury by decreasing cannulation attempts, avoids high puncture above the inguinal ligament, and enables appropriate closure device deployment. In the VQI analysis, ASCs had the highest rate of image-guided access (96.8%) and the lowest access complication rates of any setting.[7]

Vascular closure devices were associated with significantly fewer minor complications on meta-regression in the Hanna analysis (–0.039% per percentage point increase in device use, P=.032).[5] Closure devices enable earlier ambulation and reduce dependence on prolonged manual compression.

Sheath size minimization using ≤6F access where anatomically feasible facilitates faster hemostasis and earlier mobilization. The Siu et al transpedal series employed only 4F or 5F sheaths, achieving 100% procedural success in a complex high-risk population without major bleeding events.[16]

Retrograde tibiopedal access eliminates femoral puncture-associated risks entirely in suitable patients and enables treatment of complex infrapopliteal and femoropopliteal disease in the outpatient setting. Siu and colleagues demonstrated this approach in 314 patients with 2-vessel infrapopliteal CTO—the most anatomically challenging scenario, where the sole remaining nonoccluded vessel served as the access site.[16] At 6-month follow-up, there were no uncontrolled bleeding events, no procedure-related hospitalizations, and no amputations, with a mean contrast volume of only 42 mL—an advantage in a population where 43% had an eGFR below 60 mL/min/1.73 m².[16]

Structured postprocedural observation should conclude with a clinician-led assessment of the access site, distal perfusion, and overall systemic status before discharge authorization. Patients should leave with written emergency contact information, explicit education on warning signs, and a scheduled follow-up appointment within 2 to 4 weeks including ankle-brachial index measurement and duplex imaging.[5]

Economic Considerations in the U.S. Context

The economic rationale for outpatient PVI in the United States is compelling. PAD treatment accounts for over $20 billion in annual U.S. healthcare expenditure.[3,18] CMS reimbursement modifications have incentivized outpatient delivery, and the rapid growth of OBLs reflects both this policy environment and genuine per-episode cost advantages.

In patients with claudication, same-day discharge after peripheral angioplasty reduces postprocedural costs to approximately $320 per patient vs $1800 for routine overnight observation—a per-case saving of $1480.[17] At the more severe end of the spectrum, comparative analyses of ambulatory endovascular surgery vs extended inpatient stays demonstrate mean hospital costs of approximately $8200 for ambulatory cases vs over $40,000 for stays exceeding 24 hours.

The rural California findings highlight that outpatient PVI can expand access to specialist vascular care in underserved communities where the alternative is not inpatient treatment at a local hospital but no timely treatment at all.[13] In areas with higher-than-average PAD risk factors (diabetes, smoking, cardiovascular disease), the ability to deliver safe, cost-effective same-day care locally carries a meaningful impact on amputation prevention and limb salvage.

Conclusions

The evidence base for outpatient peripheral endovascular intervention is robust and directly applicable to U.S. practice. Across the international meta-analysis (99,600 procedures),[5] large-scale U.S. VQI registry data (66,101 cases),[7] OEIS Registry,[8] high-volume OBL series from academic and community centers with outcomes sustained at 36 months,[9-12] and real-world experience in rural and diabetic populations,[13,14] a consistent picture emerges: elective outpatient PVI is safe, technically effective, and does not expose appropriately selected patients to meaningfully greater risk than inpatient treatment.

Safety is equivalent across HOPDs, ASCs, and OBLs when patient selection criteria are applied. The dominant complication remains access-site hematoma, not the revascularization procedure itself. This emphasizes the importance of access site management to maximize safety (ultrasound guidance, tibial access, use of lower-profile devices). Outpatient PVI is feasible in CLI, diabetic, and rural populations when appropriate infrastructure exists. Structured patient selection, ultrasound-guided access, retrograde tibiopedal access where appropriate, and rigorous postprocedural monitoring enable outpatient endovascular procedures to be performed safely across the full spectrum of contemporary PAD patients. ■

Affiliations and Disclosures

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