

# The Value of Outpatient Based Labs for Endovascular Therapy of Peripheral Artery Disease: The Cardiovascular Institute of the South Experience

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**Abstract: Objective.** The purpose of this review from the Cardiovascular Institute of the South's (CIS) office-based lab (OBL) experience is to investigate the safety, efficacy, and patient outcomes of lower extremity endovascular intervention in patients with symptomatic peripheral arterial disease. **Methods.** Subjects that underwent a peripheral arterial intervention in the OBL setting from 2018 through 2020 were included in the study. **Results.** We found, from a random sample of 256 patients, that there were no significant complications. Procedural success, defined as inline flow to the foot with residual stenosis <50%, was found in 167 (87.4%) of the patients treated above the knee and 58 (98.3%) of the patients treated with below-the-knee intervention. **Conclusion.** The physician's choice to use the OBL at CIS for peripheral vascular intervention demonstrated safety and efficacy in all cases.

VASCULAR DISEASE MANAGEMENT 2022;19(11):E159-E162

**Key words:** office-based lab, peripheral arterial disease, peripheral vascular disease, peripheral arterial intervention, interventional cardiology

## Background

Peripheral arterial disease (PAD) affects nearly 21.3 million people in the United States<sup>1</sup> at an estimated economic cost of \$283 to \$539 billion annually.<sup>2</sup> Endovascular intervention for the treatment of PAD performed in the office-based lab (OBL) setting allows for a more efficient use of health care personnel. OBLs are defined by the Centers for Medicare & Medicaid Services (CMS) as any location, other than a hospital; skilled nursing facility; or community, public, or intermediate care facility where the health care professional routinely provides health examinations, diagnosis, and treatment of illness or injury on an ambulatory basis. Office-based surgery is defined as any surgical procedure performed by a licensed physician in the office setting requiring some level of anesthesia.<sup>3,4</sup>

The Outpatient Prospective Payment System and Physician Fee Schedule changes were made by CMS in 2008 to reflect public law changes relevant to OBLs.<sup>5</sup> In 2011, new CPT codes were created with practice expense resource-based relative value units for interventional treatments specifically for outpatient facilities. Research findings have provided evidence of the cost-effectiveness related to office-based procedures as well as the safety of patients being comparable with facilities other than OBLs.<sup>6</sup> Because of this, reimbursement rates established by CMS for many of these services have been comparable with or have exceeded hospital outpatient reimbursement.<sup>4,7,8</sup> Overall, these factors have increased the push from hospitals to OBL settings. With this has come scrutiny regarding the potential misuse and abuse of these changes.

The overall savings in the use of an OBL can be attributed to minimal overhead costs of healthcare while still maintaining a fully equipped lab, full-time anesthesiologist, and interventional ultrasound technologist; an increase in attention to efforts for reducing bleeding and complications; and no required overnight stay. This, along with the noted preference of physicians and patients for an outpatient facility as compared with other locations, makes a strong argument as to why the use of these facilities has grown rapidly over the past decade. Additionally, the use of the OBL setting increased drastically in recent times related to the COVID-19 pandemic. The situation caused a large shortage of hospital staff and a decrease in availability to reserve procedural rooms. The OBL, however, was able to continue at capacity, offering a site with less risk to the patient.

Our intent for this study is to evaluate these findings in our own practice, looking at the safety and efficacy of the peripheral interventions performed. Study success will be defined as those patients who meet both the primary efficacy and safety objectives.

## Materials and Methods

### Study Design and Patient Enrollment

This evaluation of safety and efficacy in the OBL setting was conducted as a retrospective chart review on a random sample of procedures that were performed at 3 outpatient catheterization laboratories owned and operated by the Cardiovascular Institute of the South (CIS) from January 2018 through November 2020. Subjects were filtered by procedure type to include only patients with varying degrees of PAD who were treated with an endovascular

approach. Key words included “Atherectomy Peripheral,” “PTA Peripheral,” “Stent Peripheral,” and “Cath Peripheral.” Data were further filtered to remove procedures that included veins. This resulted in 2560 patients, 923 of whom had more than 1 intervention in a single visit. Investigators chose to obtain a random sample of 10% of the data, produced by SPSS, resulting in 256 interventions for the analysis with procedures performed by 17 board-certified interventional cardiologists.<sup>9</sup>

Patient demographics and history were obtained from the electronic medical records. Ankle-brachial index (ABI) was recorded if the calculation was complete in the diagnostic study of the electronic medical record and within 6 weeks of the index procedure. The remaining patients had duplex ultrasound or computed tomography (CT) imagery. The procedure details, including access site, location of disease, previous intervention and previous stenting, lesion stenosis, residual stenosis, and complications, were obtained from the procedure reports. Procedure reports were obtained from the electronic medical records system. Procedures included percutaneous transluminal angioplasty (PTA), PTA with stent, atherectomy with PTA, or atherectomy with PTA and stent. Claudication is defined as fatigue, discomfort, cramping, or pain of vascular origin in the muscles of the lower extremities that is consistently induced by exercise and consistently relieved by rest (within 10 minutes).

### Study Outcomes and Statistical Analysis

The primary endpoint of this study was successful revascularization, defined as <50% residual stenosis to the target lesion and inline flow to the foot. The primary safety endpoint included freedom from major adverse events at time of index procedure, defined as perforation, distal embolization, need for transfer to hospital facility immediately post-procedure, need for blood transfusion, and/or death. The primary 30-day efficacy endpoint would be freedom from unplanned amputation and freedom from target lesion revascularization (TLR). Procedural failure was defined as the inability to cross a lesion or restore inline flow to the foot. Descriptive statistics were obtained for continuous variables.

### Patient Characteristics

Of the random sample taken, a total of 221 patients who underwent endovascular procedures that occurred over the course of 2 years (2018 through 2020) were reviewed. The mean age of the patient population was  $72 \pm 9$  years (range 40 to 92 years). The majority of the patient population was male (133 patients [60.18%]). The most common comorbidity was hypertension (203 [91.86%]) followed by PAD (196 [88.96%]), and the rate of current smokers was 36.1% (77) (**Table 1**). As shown in the supplementary **Table 2**, a majority of the subjects in this sample were placed in Rutherford category 3 (184 [83.26%]), while 20 (9.05%) were placed in category 4 and 18 (8.14%) were placed in category 5. ABIs were calculated in 139 of the subjects prior to target intervention. Of these, the ischemia grade was 1 or greater in 71 (51%) of the subjects with the median ABI 0.78 (interquartile range 0.62-0.91).

**Table 1. Comorbidities (by patient).**

Comorbidity	N = 221 (%)
Peripheral arterial disease	196 (88.69)
Coronary artery disease	128 (57.66)
Renal disease	31 (13.96)
Diabetes	113 (50.9)
Hypertension	203 (91.44)
Congestive heart failure	14 (6.31)
Chronic obstructive pulmonary disease	28 (12.3)
Current smoker	77 (36.1)
Former smoker	104 (45.1)

**Table 2. Rutherford classification.**

Rutherford category	N = 221 (%)
3	184 (83.26%)
4	20 (9.05%)
5	18 (8.14%)

**Table 3. Previous intervention at lesion.**

	N = 256	%
Previous endovascular therapy of target lesion	76	29.7
Previous stent in target lesion	35	13.7%

**Table 4. Stenosis grade before intervention.**

Stenosis grade	N (%)
≥96	90 (35.2)
76–96	102 (39.8)
51–75	48 (18.8)
30–50	3 (1.2)

### Procedure Characteristics

All peripheral arterial cases performed were elective procedures. With the use of ultrasound guidance for access, there were no access site complications. The target lesion was a de novo lesion in 180 (70.31%) of the subjects (**Table 3**). Of the 221 patients (256 lesions) treated, 147 (66.5%) had treatment of a single lesion above the knee (ATK), 44 (19.91%) had treatment of a single lesion below the knee (BTK), and 30 (13.57%) had treatment of more than 1 lesion either ATK, BTK, or both at a single date of intervention. For more than half the subjects, atherectomy with percutaneous transluminal angioplasty (PTA) (191 [69%]) was performed, with stents being deployed in 86 (31%)

of cases. Thirteen cases (5.08%) failed because the lesion could not be crossed. These patients were included in this analysis on an intent-to-treat basis.

Refer to supplementary **Table 4** for reference grade of stenosis prior to intervention.

In total, procedural success, defined as inline flow to the foot with residual stenosis <50%, occurred in 170 (89.01%) of the 191 lesions treated ATK and in 57 (96.61%) of the 59 lesions treated BTK. Overall, those that were not successful were cases in which the lesion was not able to be crossed due to severity of disease of luminal abnormalities (17 [6.64%]) or determined to be diagnostic (12 [4.7%]). Repeat intervention occurred within 1 year in the target vessel in 51 (19.9%) of all cases. There were no OBL mortality, major bleed, acute limb ischemia, myocardial infarction, or stroke within 72 hours of the procedure. All patients were discharged the same day. There was 1 (0.3%) emergency department visit after OBL discharge on the same day as the index procedure, for a focal hematoma with discharge happening within 24 hours. Significant amputation occurred in the target limb in 1 (0.3%) patient within 6 months (164 days).

## Discussion

The increased support by CMS and the policy change to the physician fee schedule has encouraged the use of OBLs. Furthermore, according to the 2016 *AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease*, endovascular procedures are considered to be effective as a revascularization option for patients with lifestyle-limiting claudication and who are nonresponsive to guideline-directed medical therapy (GDMT), a COE 1 LOE A.<sup>10</sup> Dual decision-making between the operator and patient with informed consent is performed with each patient to determine if OBL therapy is appropriate. Additionally, previously published literature has supported that a decrease in wait time to procedure can be observed in the OBL setting when compared with the hospital setting that shows a negative correlation with patient satisfaction and perception of physicians.<sup>11,12</sup> The average wait time at CIS is under 10 minutes. However, in those 10 minutes, registration is collecting payment information and explaining to the patient and their family the expectations of what the day should look like. The patient then returns to the lobby and is greeted by a nurse to go back for the procedure.

This review has demonstrated the use of the OBL setting for low to minimal-risk patients. It is important to recognize that the OBL at CIS is a reference lab for nearly 20% of patients who have failed treatment elsewhere. The American Society of Anesthesiologists (ASA) classifications for the procedures include ASA I, 63.9%; and ASA II, 36.10%. None of the patients were classified as ASA III-VI.<sup>13</sup> In this sample, the investigators were able to identify that in the cases where patients were determined to be complicated (11 cases [4%]), the procedure was stopped and the patient scheduled for a later date to be performed in the hospital setting. Complex procedures needing advanced techniques often preferred to be completed by physicians in the OBL setting because of the dedicated staff who are trained specifically in endovascular interventions and the optimized tools available for

the procedures.<sup>14</sup> Safety is undoubtedly the number one priority for patients, and they receive more direct attention while in the OBL setting as there are typically minimal procedures happening simultaneously.

## Limitations

This study was a chart review and relied on the accuracy of procedure and follow-up notes. The data collected were formed by computer-generated random sampling. We would have liked to include patient satisfaction; however, due to new program implementation, there were not yet ample response rates to analyze.

## Conclusion

This review suggests the use of the OBL for performing endovascular treatment in the peripheral arterial system by CIS physicians who have followed guidelines and chose to treat patients with only a low/moderate procedural risk demonstrates the safety and efficacy of the use of the OBL in performing peripheral endovascular procedures. ■

*Disclosure: The authors have completed and returned the ICMJE Form for Disclosure of Potential Conflicts of Interest. The authors report no conflicts of interest regarding the content herein.*

*Manuscript accepted October 7, 2022.*

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