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Implementing Outpatient Screening of Adult Patients at High Risk for Peripheral Artery Disease

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IMPLEMENTING OUTPATIENT SCREENING OF ADULT PATIENTS AT HIGH RISK FOR PERIPHERAL ARTERY DISEASE

By

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Abstract

Background: Peripheral artery disease (PAD) is a prevalent chronic vascular disease that remains often underdiagnosed and inadequately treated. The development of PAD increases both with age and with the presence of modifiable and non-modifiable risk factors. Risk factors for PAD include smoking, diabetes, hypertension, hyperlipidemia, and chronic kidney disease. Furthermore, PAD can be an indicator of systemic atherosclerosis which is associated with coronary artery disease, carotid stenosis, and cerebrovascular disease. Undiagnosed obstructive PAD contributes to damaging atherosclerotic sequelae such as claudication, ulcers, infections, peripheral neuropathy, and amputations. It is common for PAD to exist in the absence of symptoms; therefore, providers should prioritize the screening of patients with known risk factors. **Purpose:** The aim of this evidence-based project was to introduce the American Heart Association/American College of Cardiology (AHA/ACC) standardized ABI screening statement to improve patient outcomes in an outpatient cardiology center by screening high risk asymptomatic patients utilizing the ankle-brachial index (ABI). According to the AHA/ACC, when ABI is used to assess high-risk asymptomatic patients then risk factor mitigation such as lifestyle modifications and pharmacological treatment can be implemented. This retrospective-prospective project compared the frequency of ABI ordering pre/postintervention and collected pertinent demographics (e.g., risk factors, symptoms, physical examination findings, and ABI screening results). **Results:** The results will demonstrate that the implementation of ABI screening protocol resulted in a statistically significant increase, by 31.6%, in the frequency of ABI ordering for patients that presented with physical signs and symptoms (e.g., lower extremity discoloration, hair loss, or paresthesia). Although provider-usage of ABI screening for asymptomatic patients did not significantly increase, postintervention ABI orders saw a 15%

increase when compared to pre-intervention ABI orders. **Conclusion:** With integration into clinic policies, this project can be adapted to other outpatient cardiac centers using the AHA/ACC standards for ABI screening.

Keywords: peripheral artery disease, ankle brachial index, screening, risk factors, evidence-based practice change

Implementing Outpatient Screening of Adult Patients at High Risk for Peripheral Artery Disease

The patient population of the outpatient cardiology clinic is elevated risk for the development of atherosclerotic diseases (Campia et al., 2019; Firnhaber & Powell, 2019). This project was designed to identify asymptomatic patients with underlying atherosclerotic pathology in the lower extremities. Often, disease processes remain undetected until physical signs or symptoms develop (Campia et al., 2019; Firnhaber & Powell, 2019). Identification of asymptomatic disease allows for treatment plan changes as indicated (Campia et al., 2019; Firnhaber & Powell, 2019).

Background and Significance

Peripheral artery disease (PAD) is a chronic vascular disease. The incidence of PAD increases with the patient's age, yet often remains frequently under diagnosed and undertreated (Campia et al., 2019; Firnhaber & Powell, 2019). The likelihood of developing PAD increases with the presence of each additional comorbid risk factor: smoking history, diabetes mellitus, hypertension, hyperlipidemia, and chronic kidney disease (Firnhaber & Powell, 2019; Toth-Vajna et al., 2019). Though some analyses have indicated that there may be risk factors that are difficult to screen for, such as a patient's racial/ethnic groups (Matsushita et al., 2019). A diagnosis of PAD can be an indicator of systemic atherosclerosis which is found in the disease states of coronary artery disease and cerebrovascular disease (Aboyan et al., 2012; Campia et al, 2019). Undiagnosed obstructive PAD contributes to significant atherosclerotic sequelae such as claudication, ulcers, infections, critical limb ischemia and amputations (Aguirre et al., 2022; Campia et al, 2019). PAD can exist in the absence of symptoms; therefore, providers should prioritize the evaluation of asymptomatic patients diagnosed with known risk factors (Campia et

al., 2019). Early detection of PAD allows the patient and provider opportunities to initiate lifestyle modifications and pharmaceutical therapies. The changes can interrupt the disease process and prevent disease sequelae (Campia et al., 2019; Firnhaber & Powell, 2019).

Ankle Brachial Index (ABI) is a noninvasive measurement and screening tool which can serve as a prognostic marker for PAD in the absence of acute symptoms (Aboyans et al., 2012). The ABI is a ratio of the blood pressure measured in the lower extremities compared to that measured in the upper extremities (Aboyans et al., 2012; Campia et al., 2019; Firnhaber & Powell, 2019). An ABI threshold of ≤ 0.9 can have sensitivity ranging from 79 to 97% to detect the presence of PAD, although this sensitivity can be reduced in the presence of diabetes (Aboyans et al., 2012; Firnhaber & Powell, 2019; Toth-Vajna et al., 2019).

Currently, the American Heart Association/American College of Cardiology (AHA/ACC) recommends resting ABI measurements for any patients with clinical signs of PAD, including diminished lower extremity pulses, discoloration, hair loss and nonhealing ulcers (Gerhard-Herman et al., 2016). The AHA/ACC guideline recognizes two critical research gaps: the use of ABI testing in asymptomatic patients and a clinical classification system incorporating patient-specific risk factors (Gerhard-Herman et al., 2016). Matsushita et al. (2019) has started to address the research gap for a patient specific clinical risk calculator; however, currently providers can only screen for PAD based upon key risk factors and patient symptoms. According to Gerhard-Herman (2016), all patients presenting with a history or physical findings suspicious for PAD, should be screened via resting ABI. Numerous studies corroborate the importance of screening using ABI in patients at increased risk, because a positive result can indicate disease pathology before the onset of symptoms (Heald et al., 2006; Toth-Vajna et al., 2019). Of note, the USPSTF still does not recommend screening asymptomatic patients, that are not at increased

risk for developing PAD, because there is insufficient evidence of the harms and benefits (United States Preventative Services Task Force, 2018).

To correctly measure an ABI, the patient should be positioned in a supine position with both the head and legs supported (Aboyans et al., 2012). Ideally, the cuffs for both the upper and lower extremities will be at least 40% of the limb circumference (Aboyans et al., 2012). The American Heart Association (AHA) recommends utilizing a doppler probe for detection of arterial flow (pulse), at the posterior tibial or dorsal pedalis sites, as the pneumatic cuff is inflated (Aboyans et al., 2012). Inflation of the cuff continues until arterial flow ceases and then deflated until the flow reappears – this value is the systolic blood pressure (SBP) (Aboyans et al., 2012). These steps are completed in each limb; the higher value between both arms is used as the denominator in comparison to the values of each lower limb as the numerator (Aboyans et al., 2012). Utilizing the highest SBP readings increases the specificity of the ABI and reduces misdiagnosis in healthy patients (Aboyans et al., 2012). ABI values indicative of PAD are ≤ 0.9 would warrant intervention by the healthcare provider (Firnhaber & Powell, 2019). Although ABI measurements are noninvasive, there are contraindications that include acute pain during measurement, direct contact of the cuff with an ulcer and if the patient has recently undergone a lower extremity bypass graft (Aboyans et al., 2012). Burke et al (2020) demonstrated ABI measurements do not change quickly, therefore repeat screening within 10 years is rarely required. The relative safety and noninvasive nature of ABI measurements makes them ideal for outpatient clinics.

Based on the evidence, positive ABI readings should not be considered diagnostic for PAD (Aboyans et al. 2012). With that consideration, noninvasive diagnosis should be confirmed with either an ultrasound assessment of the lower extremity arteries (LEA) or computed

tomographic angiography (CTA) of the lower extremities (Firnhaber & Powell, 2019; McDivitt et al., 2019). Standard of care for the treatment of peripheral artery disease includes lifestyle management, pharmaceutical management, management of comorbid disease states and surgical revascularization (Campia et al., 2019; Firnhaber & Powell, 2019). Lifestyle management techniques include smoking cessation, structured exercise, and other atherosclerotic interventions, such as diet modifications (Campia et al., 2019; Firnhaber & Powell, 2019). Pharmaceutical management standards currently recommend statin regimens, antiplatelet management, or combined anti-platelet/ anti-thrombotic therapies, and anti-hypertensives (Anand et al., 2018; Campia et al., 2019; Firnhaber & Powell, 2019). For patients with significant disease, combination therapy including surgical revascularization, physical rehabilitation and pharmacotherapy can control significant symptom control (Fakhry et al., 2018). PAD has significant impacts upon a patient's quality of life and overall health with such extensive treatment modalities, diagnosis and mitigation of disease progression should be a priority.

Methods

Purpose and Literature Search

This project was guided by one primary investigative question to answer whether ABI would be an appropriate screening tool for high-risk asymptomatic patients in the outpatient management of adult patients with risk factors for peripheral artery disease. Does screening asymptomatic patients with ankle-brachial index, compared to screening only those are symptomatic, result in earlier pharmacological treatment or vascular surgery referral? The following search terms were used to answer the research question: peripheral artery disease, PAD, risk factors, ankle brachial index, ABI, lower extremity arterial, LEA, clinical practice

guidelines, recommendation from professional organizations. These terms were used to search CINAHL, PubMed, Cochrane Database of Systematic Reviews and US Preventative Services Task Force databases. The initial review of evidence provided 22 articles, statements, systematic reviews, and clinical practice guidelines.

Evidence-Based Practice Model

This evidenced-based practice (EBP) project was designed and guided based on the Iowa Model (IM). The IM was selected because of its cyclical design and simplistic approach to reformulation of the project as needed. A strength of the IM is the emphasis placed on selecting a PICO(T) question that is a priority for the organization in which the project is implemented (Cabarrus College, 2022; Melnyk & Fineout-Overholt, 2019). Selecting an evidence- based practice (EBP) project that supports the needs of the organization ensures stakeholder buy-in (Cabarrus College, 2022; Melnyk & Fineout-Overholt, 2019). This evidenced-based practice project was requested by the clinic, demonstrating the prioritization of this PICOT outpatient cardiology clinic.

Implementation

This evidence-based project was designed as a retrospective data analysis comparing the frequency of ABI ordering before and after provider education. Provider education included a brief verbal in-service regarding PAD, risk factors, physical findings indicative of PAD, validity of ABI and appropriate PAD treatments and printed quick reference guides, see Appendix A.

Preintervention, retrospective baseline data included patient demographics, presence of risk factors, patient reported symptoms, physical examination findings, ABI orders, and ABI results. The retrospective patient population was provided from information technology (IT)

services utilizing the following search parameters, “peripheral artery disease and claudication” and “18 years and older.” Following the date of provider education, similar data were collected utilizing the same terms IT and personal patient encounters. All data were collected from electronic health record (EHR) review.

Cost Benefit Analysis and Return on Investment

Implementation of this project provided the most financial benefit to the clinic if the patient identified as at-risk were screened, utilizing ABI, at a subsequent appointment. When all costs were considered, including longer appointment times, staff training, and one-time costs for educational materials, the cost benefit analysis (CBA) was positive (American College of Cardiology, 2017; Pierce, 2021; Salary.com, 2022a; Salary.com, 2022b). The CBA indicated that the implementation of the program would net $1.08 for the initial patient with an initial return on investment (ROI) of 0.08%. The subsequent ROI for any additional patients could be as high as 551%. When properly implemented and maintained, this evidence-based practice change demonstrated that it could be financially beneficial to the clinic, which would reinforce stakeholder buy-in and long-term sustainability. Current clinic policy is to schedule urgent/emergent ABI screenings within 1 day and all non-urgent screenings within 4 weeks.

Outcomes

Results

Data analysis indicated providers at the cardiology clinic routinely referred symptomatic patients for PAD screening, utilizing the noninvasive ABI technique, but often missed asymptomatic patients. After project implementation, providers continued to successfully refer symptomatic patients; however, despite education, providers continued to miss opportunities for asymptomatic patients with comorbid risk factors.

As seen in Table 1, the various patient demographics were similar between the retrospective comparison group and the postintervention group. Between both groups there were a total of 46 patients: 20 in the preimplementation phase and 26 after EBP intervention. Patient ages ranged from 54 to 93. The demographics were equally distributed between pre and post intervention groups except for the age group, 50 to 59. The post-implementation group had three times as many participants in this age bracket. The female to male ratio was also consistent between groups.

The distribution of diagnosed risk factors is displayed in Figure 1. Hypertension and hyperlipidemia were the most prevalent risk factors in this sample of the clinic patient population. Overall, the preintervention participant group had lower risk factors rates when compared to the postintervention group.

The ABI completion rates of both symptomatic and asymtpomtic patients, in pre and post interventions groups, are compared in Figure 2. ABI screening was indicated for all but one of the project participants based upon the presence of risk factors, signs or symptoms. Only one patient, in the postintervention group, had a contraindication for completing the ABI. Patients were considered symptomatic if they presented with either physical signs or patient reported symptoms. Regardless of patient risk factors, the presence of signs or symtpoms validated screening for PAD with ABI. Asymptomatic patients included those that had risk factors and did not have any current physical signs or symptoms. This group was the targeted population for this evidence based practice project.

In the preintervention group, fourteen symptomatic patients were correctly identified and screened with an ABI for the presence of PAD. Providers noted PAD signs or symptoms in fifteen patients; 86% of these patients were referred for ABI screening. Five patients were high

risk for the development of PAD secondary to the presence of known risk factors; 80% of these patients did not receive an ABI screening in the preintervention group. Four of the five asymptomatic patients that met criteria for ABI screening based on risk factors, were erroneously classified which resulted in missed opportunities for early diagnosis of PAD.

Data from the postintervention group revealed that 88% of the patients were symptomatic when compared to the 75% of the preintervention group. It is likely that the increased frequency of signs and symptoms correlate to the higher rate of risk factors in the postintervention group. Six of the 23 symptomatic patients (26%) did not receive appropriate ABI screening. Missed appointments and scheduled ABI exams beyond the end date of this project contributed to this value, though it was not substancially different from the 24% of the preintervention group. In the postintervention group, three patients met the target group criteria. Two of the three patients were not correctly targeted for ABI screening. After provider education and project implementation, 66% of high risk asymptomatic patients were still not undergoing screening for PAD.

Figure 3 displays the 31 ABI exams that resulted in calculable results. Twenty eight percent of the pre-intervention group had ABI results ≤ 0.9 and were indicative of PAD. Of the postintervention group, 35% had positive results. In both groups, two ABI screenings resulted in ratios considered non-calculable. These patients cannot adequately be screened with ABI which warrants additional diagnositcs. Eighty eight percent of the clients that had ABI exams had results of clinical value. When considering positives results, the worse result of the two was recorded.

Figure 4 demonstrates that positive ABI exams resulted in changes to a patient's plan of care. In total, four patients had therapies initiated to treat PAD. These therapies included lifestyle

modifications, pharmaceutical regimens or referrals to vascular surgeons. Although only 11% of the total project participants, these four patients represent proactive health care. In the cases of these four patients, they were screened because they were symptomatic. None of the asymptomatic patients, screened based only on risk factors, required treatment plan changes.

Conclusion

Barriers to Project Implementation

Implementation of this project was not without barriers. Retrospective data collection skews patient selection based on search phrases and electronic health record categorization. These factors can change over time and with various providers. Although the demographics of the patient pool were well balanced, the total cohort was small. It is possible that with a larger sample size of the clinic's patient population, the results may demonstrate that a larger percentage of the target population was evaluated and hopefully tested and treated. In addition, this project was completed at a cardiology office. Many of these patients presented with atherosclerotic sequalae, meaning that even if subsequently diagnosed with PAD, these patients often are already established on appropriate PAD treatments.

Discussion

Data supports that symptomatic patients often receive appropriate ABI screening. Completion of ABI for high-risk asymptomatic patients continued to be frequently missed despite project implementation. However, screening symptomatic patients with ABI did result in treatment intiation for new PAD diagnoses.

Project results were shared with the clinic providers via a stakeholder presentation. This evidence-based practice project, when fully implemented and integrated, could have a substantial financial ROI for the clinic. Additionally, patients would be treated proactively to identify

disease processes before long-term and often irreversible damage develops. Sustainable implementation of this practice change would benefit from providing recurring education for providers. This education should include information regarding patient-specific risk factors that trigger ABI screening. Long-term implementation could also be achieved through EHR modifications such as, practice alerts based on patient criteria. Additionally, strict management of the most prevalent risk factors, hypertension and hyperlipidemia, could positively impact the prevalence of PAD in this clinic's patient population. Future projects could include investigating the benefit of introducing this evidence-based practice in a primary care setting. ABI provides a relatively quick and inexpensive measure of the presence of PAD. Early identification based solely the presence of risk factors can lead to earlier diagnosis and treatment plan changes.

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Table 1

Patient Demographics

Baseline Charcateristic		Pre-Implementation		Post Implementation		Total	
		n = 20	%	n = 26	%	n = 46	%
Sex							
	Female	12	60%	13	50%	25	55%
	Male	8	40%	13	50%	21	45%
Age							
	≥80	6	30%	8	30%	14	30%
	70-79	7	35%	7	26%	14	30%
	60-69	6	30%	8	30%	14	30%
	50-59	1	5%	3	14%	4	10%
	<50	--	--	--	--	--	--

Figure 1

Distribution of Risk Factors Among Participants

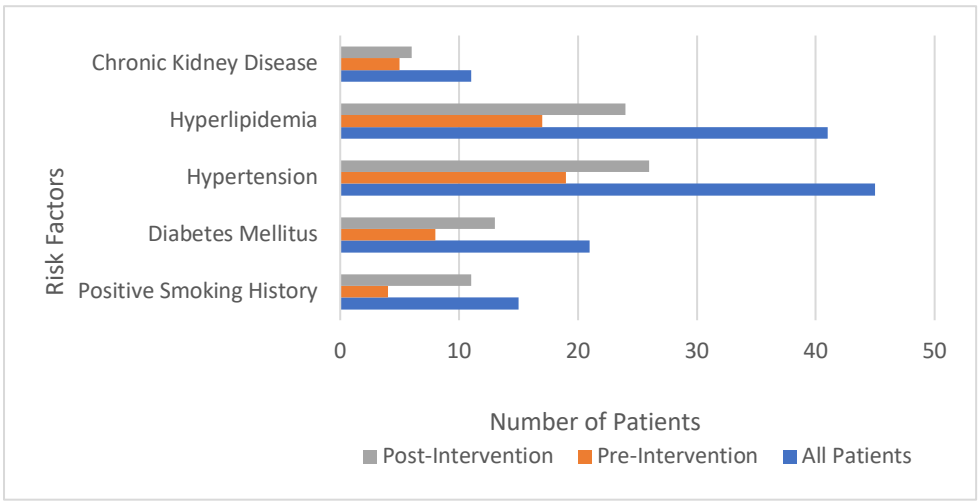
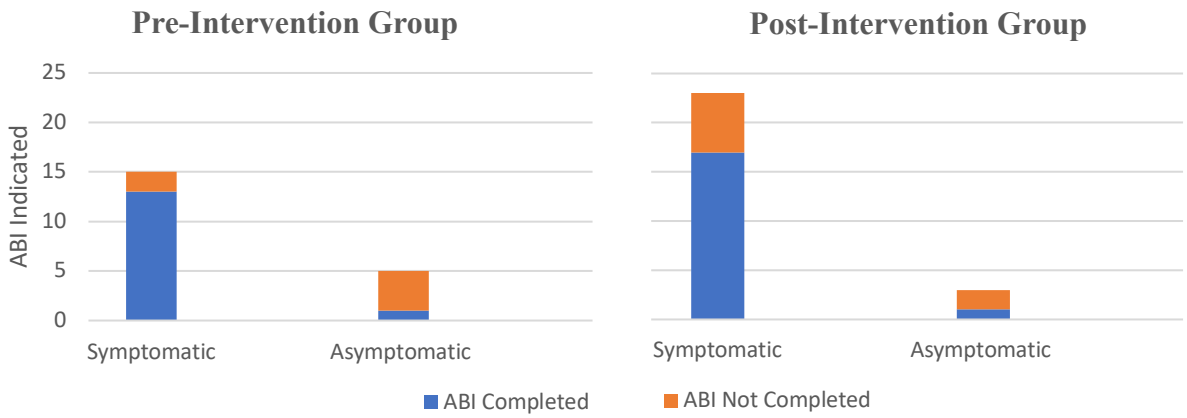


Figure 2

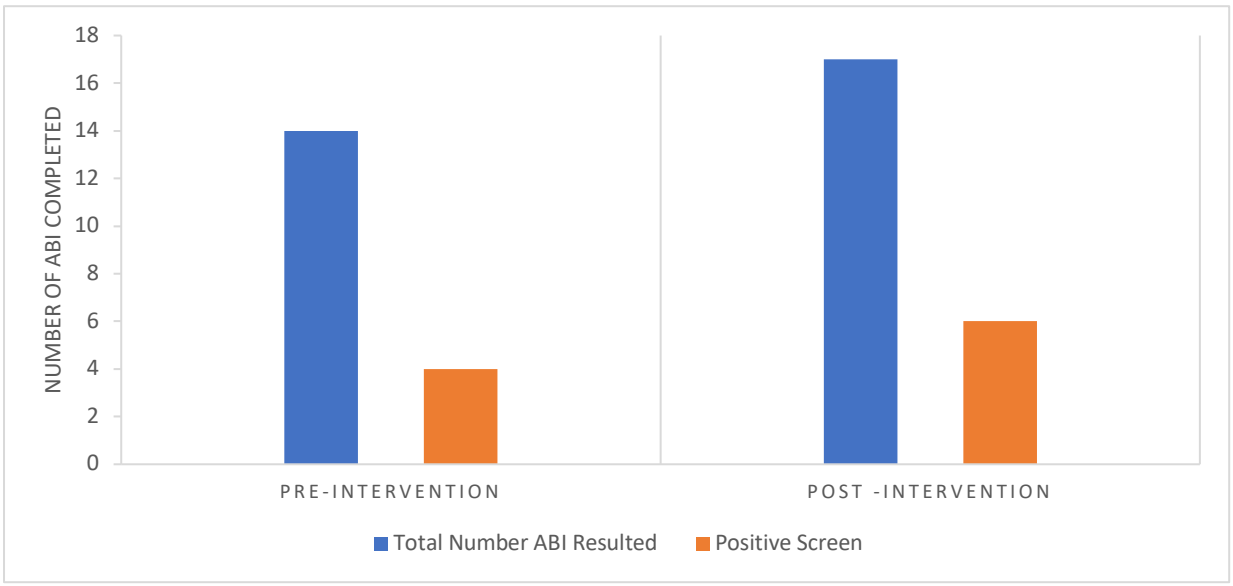
Successful ABI Screening in Symptomatic and Asymptomatic Patients



Note. ABI = Ankle Brahcial Index

Figure 3

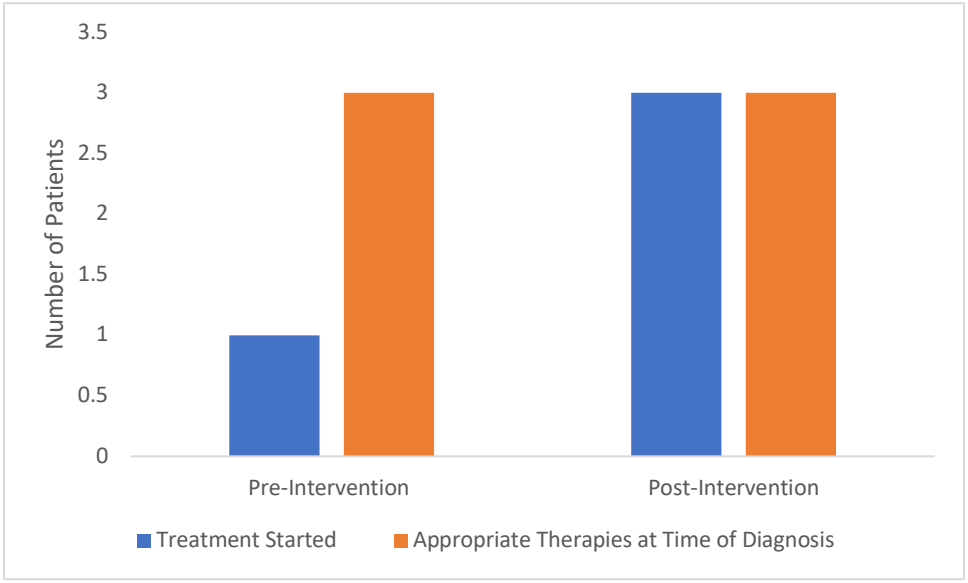
Positive ABI Results



Note. ABI = Ankle Brahial Index

Figure 4

Appropirate Treatment Evaluation in Patients with Positive ABI Results



Appendix A

Quick Reference Guide

Ankle Brachial Index Ordering Indications

Presence of Risk Factors
• Smoking History (Current or Former) • Diabetes (Type I or II) • Hypertension • Hyperlipidemia • Chronic Kidney Disease
Presence of Symptoms
• Intermittent Claudication • Ischemic Pain at Rest • Paraesthesia
Presence of Physical Symptoms
• Pallor/ Color Changes • Diminished Pulses • Hair Loss • Non-Healing Wounds

If your patient has *at least two criteria* in any of the three categories, **consider** screening for peripheral artery disease with an ankle brachial index (ABI) scan.

Your patient **high risk** for peripheral artery disease if they have at least one criterion in each category. Screening with ABI is *highly recommended* in this group.