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Implementation of an Evidenced Based Peripheral Artery Disease Screening Protocol in an Outpatient Internal Medicine Clinic

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Manuscript: Implementation of an Evidenced Based Peripheral Artery Disease Screening Protocol in an Outpatient Internal Medicine Clinic

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Abstract

Purpose: The purpose of this evidenced based project was to implement an evidenced based peripheral artery disease screening protocol in an outpatient internal medicine clinic serving adult patients with multiple co-morbidities. This clinic inconsistently screened patients for PAD using the ankle-brachial index (ABI).

Methods: During a three-month period, 50 patients were screened using current American Heart Association and American College of Cardiology (AHA/ACC) screening guidelines for PAD using the Ankle-Brachial Index (ABI) and the Edinburgh Claudication Questionnaire (ECQ).

Results: Out of the 50 patients screened for PAD, only one patient (2%) had a normal ABI score (1.0-1.4) and was categorized in group two of the AHA/ACC risk groups. In group one, 16 patients (32%) had a borderline ABI score (0.8-1.0), group two had 23 patients (46%) with a borderline ABI score, and group three had two patients (4%) with a borderline ABI score. Finally, group one had two patients (4%) with abnormal ABI scores (0.5-0.8), group two had six patients (12%) with abnormal ABI scores, and group three had none. Seven patients scored a positive ECQ and six of these patients (12%) were categorized in risk group two, and the single remaining patient (2%) with the positive ECQ score was categorized in risk group one.

Evaluation: The project was done within a 3-month timeframe, which prevented follow up measurements of ABI scores in patients at risk of developing PAD. The short duration also prevented long term measurement of outcomes in patients who had decreased ABI scores requiring referral to a vascular specialist. Future projects could include outcome measurements of those requiring referral, and those whose risk factors were addressed.

Keywords: Peripheral Artery Disease, Ankle-Brachial-Index, Edinburgh Claudication, Screening

Background and Significance

Peripheral artery disease (PAD) is defined as blockage of blood flow through the arteries and veins in the upper and lower extremities. The blockages are primarily caused by a buildup of fatty deposits called plaque. The buildup of plaque over time can cause blockage of adequate blood flow to the arms and legs, causing the patient claudication, edema, and slow healing skin ulcers. About 6.5 million people over the age of 40 in the United States have peripheral artery disease. Identification of modifiable risk factors and implementation of preventative screening remains low in primary care settings. Identifying patients at risk for PAD and implementing primary prevention strategies early in the disease process will reduce unnecessary primary care and ED visits, reduce annual health care costs, and improve quality of life (QOL) for the patient.

According to current literature, this seems to be multifactorial in cause due to limited knowledge of how to implement ABI, limited availability of first line diagnostic testing such as the use of a venous doppler ultrasound and the perception that the diagnosis of PAD would not change or improve clinical practice. This seemed to be true in the small, private, internal medicine clinic this project was implemented in. Routine screening for PAD in high-risk patients coming in for their annual physical exams was not current practice and was seldom done unless the patient complained of claudication pain during a visit. No evidenced based screening protocol for PAD was in place.

Purpose and Goals

The purpose of this project is to fill a practice gap that could largely be of benefit to the patient population served in this internal medicine clinic. Patients seen in this clinic consist of adult patients with multiple chronic conditions and comorbidities. Conditions such as hypertension (HTN), hyperlipidemia (HLD), diabetes mellitus (DM), current or former smokers

or nicotine users were among the most common conditions seen in clinic. These patients could easily benefit from PAD screening since most if not all their chronic conditions fit the profile of patients at risk for PAD. Implementation of an evidenced based PAD screening protocol can be performed during the patient's annual wellness exam where a complete physical exam, medication reconciliation and other screening interventions are done.

The first goal of this evidenced based project would be to identify any knowledge gaps regarding PAD screening from the providers and clinical staff. Majority of the medical assistants and nursing staff have had experience in collecting systolic ankle pressures in clinic albeit not performed daily. Since most of the staff had skills in taking a manual blood pressure and how to operate a portable venous doppler, reviewing how to take an accurate manual ankle systolic pressure was not an issue. Education was mostly focused on what PAD is, what causes it, and what types of patients would be appropriate candidates for screening. The second goal would be to refine the current clinic practice of inconsistently screening patients for PAD. This would require using current evidence from the literature to see what the recommended practice guideline for screening patients at risk for PAD is.

Evidenced- Based Practice Model

The model used for this project was the John Hopkins Nursing Evidenced Based Practice Model (JHNEBP). This model was developed by a team of Johns Hopkins researchers and nurses to simplify the implementation process of new knowledge and evidence into current nursing practice. The JHNEBP Model includes a conceptual model, PET Process (Practice Question, Evidence, and Translation), and tools to guide nurses through each step of the EBP process (Melnyk & Fineout-Overholt, 2019). The JHNEBP model begins with inquiry related to a specific problem or a particular patient population. Once inquiry sparks interest in a specific

problem, the PET Process can begin, which helps the nurse or advance practitioner to develop a refined practice question, conduct a literature review to seek out the best evidence, and translate the best evidence into current practice (Dang & Dearholt, 2018). The PET process is integral to the JHNEBP model because each of the three phases of the PET process has 19 iterative steps that allow fluidity and constant evaluation of the EBP process.

The JHNEBP model is appropriate for this project because it is a dynamic process that allows incorporation of new evidence into best clinical practice while ensuring constant evaluation, feedback, and improvement in relation to the specific clinic workflow. Working through the JHNEBP model encourages an individual, or in this instance the clinical team, to gain and incorporate new knowledge that will improve patient outcomes (Melnyk & Fineout-Overholt, 2019).

Literature Review and Evidence for the Problem

A literature review was performed prior to planning, design, and implementation of the evidenced based project. PubMed, MEDLINE and CINHAL were the database engines utilized to pull relevant and current literature. MeSH terms used included ankle brachial indices, brachial index, toe-brachial indices, peripheral artery disease, ankle brachial index, prevention screening, peripheral artery disease risk, and asymptomatic peripheral artery disease. These search results returned four level I articles, two level III articles, and one level IV articles. The sources of evidence were evaluated and compared using a hierarchy level and evidence summary table for analysis and review.

A systematic review was done by Casey et al. (2019) to evaluate the reliability of the ankle brachial index (ABI) as a noninvasive method to detect the presence and severity of peripheral artery disease (PAD). The results of their review concluded that the ABI is a reliable

tool to detect the presence of PAD. However, the authors determined that inconsistencies with obtaining manual systolic pressure measurements, and correct calculation of ABI values made it difficult to determine the validity of the ABI (Casey et al., 2019). Kieback et al. (2019) examined various studies comparing ABI versus a claudication questionnaire such as the Edinburgh Claudication Questionnaire (ECQ) as a screening tool for PAD in asymptomatic individuals. This meta-analysis concluded that even though the ECQ can aid in identifying patients at risk for PAD and thus would benefit from screening, the ECQ would not negate the advantages of PAD screening by ABI measurement in asymptomatic individuals (Kieback et al., 2019). Uyagu et al. (2022) performed a systematic review and comparative analysis regarding recommendations of current guidelines on screening and diagnosis of PAD. Their study found that using ABI in conjunction with clinical history and physical exam for the initial diagnosis of PAD as solid evidence for screening in individuals as risk, except in those with a history of hardened arteries which could skew ABI readings and provide false positive results (Uyagu et al., 2022). Donohue et al. (2019) conducted a systematic review examining the reliability and validity of PAD screening tools in non-neuropathic lower leg ischemia. The authors found that the traditional ABI was a reliable, valid lower leg ischemia screening tool for patients at risk for PAD and thus would require a referral to a vascular specialist for a concise diagnosis (Donohue et al., 2019).

In a non-randomized control trial done by Tóth-Vajna et al. (2019), they screened eight hundred and sixteen patients in a primary care setting for PAD using the ABI and ECQ based off the individual medical histories, current medications, and major risk factors for PAD. Their study found that utilizing ABI with ECQ had statistically significant differences in PAD-positive patients with positive ABI and ECQ scores versus PAD-positive patients with past medical

histories of active smoking, hypertension, and previous PAD diagnosis. This meant that a fraction of the PAD-positive patients with the above-mentioned diagnoses had a higher incidence of being ABI-negative but with symptomatic PAD. They concluded that the use of ABI and ECQ in patients without a prior history of PAD, prior myocardial infarction, prior stroke, and current smoking status were reliable screening methods for PAD (Tóth-Vajna et al., 2019). A cohort study done by Matsushita et al. (2019) utilized data from six community-based cohorts representing various ethnic backgrounds (African Americans, Caucasians, Hispanics), gender (Male, Female) and age. They found that the use of ABI for PAD screening regardless of ethnic background, gender or age remained consistent despite various baseline risk factors prevalent for each categorical cohort (Matsushita et al., 2019). In a population based observational study done by Sartipy et al. (2022), the authors identified 559 out of 8000 patients to have some degree of PAD using ABI and identification of accompanying lower limb symptoms. The patients were classified using cardiovascular (CV) risk factors in addition to their overall 10-year CV risk outcome. Their study concluded that ABI measurements should be used as a screening tool for patients at risk for PAD and to address modifiable risk factors in those whose ABI falls just below a normal ABI score of 0.9 (Sartipy et al., 2022).

Current screening guidelines for diagnosis and management for PAD from the American Heart Association (AHA), American College of Cardiology (ACC), and the United States Preventative Screening Task Force (USPSTF) do not recommend screening asymptomatic patients in the absence of risk factors, history, or signs and symptoms of PAD (Virani et al., 2021). However, screening is warranted in populations using resting ABI in patients with the following conditions: older than 65 years old, ages 50 to 64 years old with at least one atherosclerotic risk factor (ever smoked, diabetes mellitus, hypertension, hyperlipidemia, or

family history of PAD), or younger than age 50 years old with diabetes mellitus and one atherosclerotic risk factor (Kithcart & Beckman, 2018).

The clinic this project was implemented in serves high risk adult patients with multiple comorbidities. This means most patients that are seen daily have or are at risk for HTN, HLD, DM, obese or are current smokers. This population could benefit from PAD screening utilizing the ABI and ECQ. Many of these patients have CVD risk factors that can be positively modified using early identification of those risk factors (RF) accompanied with aggressive implementation of prevention strategies to slow their progression of PAD as suggested by current evidence.

Description of Evidenced- Based Project and Methods

This evidenced based project was designed specifically for the providers and patients in mind. A total of 50 patients were screened for PAD who were scheduled to come in for their annual physical exams. We used current AHA/ACC screening guidelines for PAD which include the use of the ABI and ECQ. Before patients could be screened, they were identified to have one of the following atherosclerotic risk factors according to current AHA/ACC guidelines. These atherosclerotic risk factors include age (between 50 to 65 years old), HTN, HLD, hemoglobin a1c (for patients with diabetes), a current diabetes type 2 diagnosis, and current or former nicotine use. The purpose of this initial step was to avoid inappropriately screening patients who were not at risk for PAD.

After the appropriate patient was identified, we then calculated resting ABI in patients with the following conditions: older than 65 years old, 50 to 64 years old with at least one atherosclerotic risk factor (ever smoked, DM, HTN, or personal family history of PAD), or younger than 50 years old with diabetes mellitus with at least one atherosclerotic risk factor. Once ABI was calculated we administered the ECQ to determine if there was claudication pain

accompanying a decreased ABI. The ECQ is a questionnaire that is tailored to identify whether the patient is having pain during ambulation. If the patient states yes, the questionnaire continues with another set of questions asking if the pain improves or worsens with rest, the quality of pain (aching, cramping), what part of the lower extremities have pain (calf, buttocks, thigh), and to differentiate the level of difficulty and physical effort the patient exerts during ambulation.

Intervention is based off the ABI value. An ABI value between 1.0-1.4 is considered normal and requires no additional treatment. An ABI level between 0.9-1.0 is acceptable and requires no treatment except to continue prevention and management of modifiable risk factors. An ABI value between 0.8-0.9 indicates some arterial disease, current recommended treatment entails aggressively preventing and managing modifiable risk factors (HTN, HLD, DM, nicotine use) as a strategy to prevent PAD from progressing. These patients were advised to follow up in 3 months to assess their progress and remeasurement of their ABI. Patients whose ABI values fall between 0.5-0.8 indicate moderate arterial disease, and ABI values less than 0.5 are suggested to have severe arterial disease. According to current AHA/ACC guidelines for PAD screening, patients whose ABI fall between 0.8 to below 0.5 should be referred to a vascular specialist for more diagnostic testing such as a venous doppler ultrasound to confirm diagnosis of PAD, along with continued management of atherosclerotic risk factors. Patients whose ABI is below 0.8 should also have an ECQ given to determine if there is any degree of intermittent claudication pain.

Ethical Considerations

This author underwent the Collaborative Institutional Training Initiative Program (CITI) through the University of San Diego's Institutional Review Board (IRB). The study was approved as exempt by the IRB at the University of San Diego, Hahn School of Nursing.

Additional IRB approval was not required as the project was implemented in a private practice and has no relation to another healthcare organization. Therefore, IRB approval was exempt as this was an evidenced-based practice project. There was no funding received or conflicts of interest in this evidenced-based practice project.

Results of Evidenced-Based Project

To disseminate the results in an organized manner, patients were divided upon three groups based off the AHA/ACC risk category for PAD. Patients aged 65 or older were categorized as group one. Patients aged 50 to 64 with atherosclerotic risk factors were categorized into group two. Finally, patients younger than 50 with diabetes and or an atherosclerotic risk factor were categorized as group three. We screened a total of 50 patients. A complete descriptive analysis is illustrated in table one.

Table 1

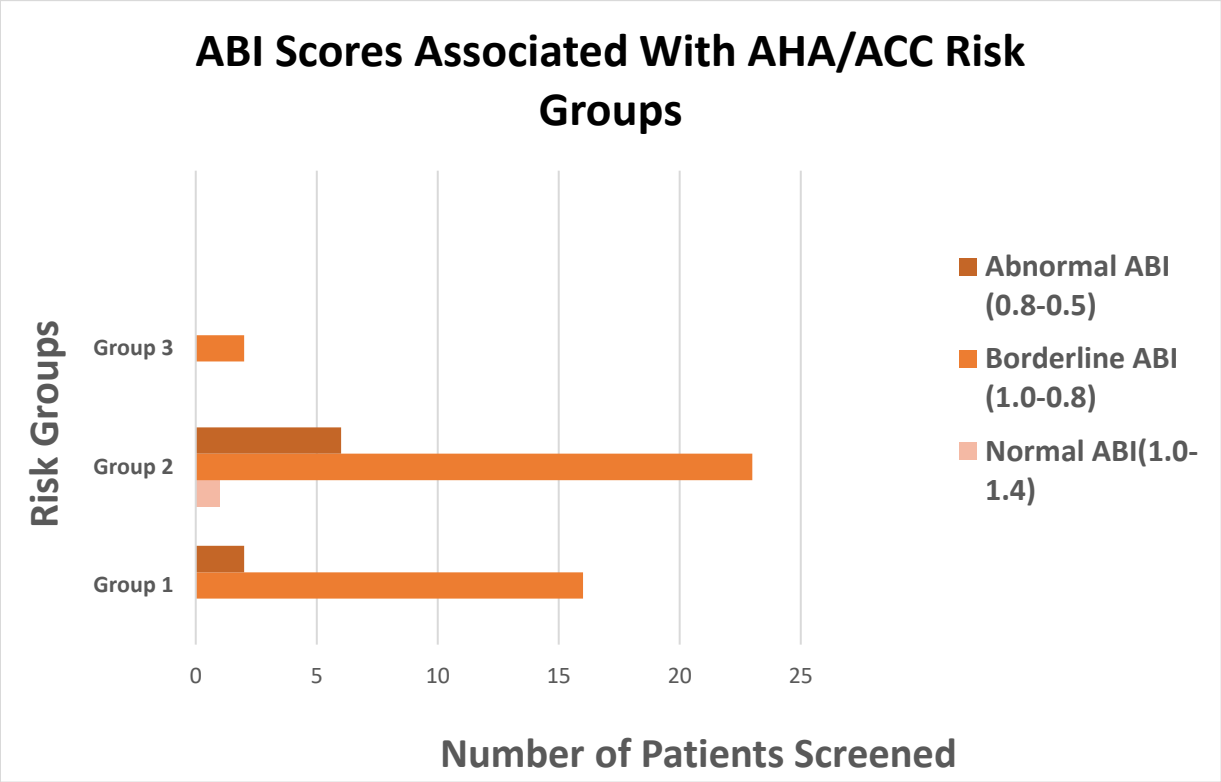
Screened Patients Categorized Into AHA/ACC Risk Groups For PAD

Group 1: Patients 65 years or older → 19 patients
Group 2: Patients 50-64 years old w/ Atherosclerotic RF → 29 patients
Group 3: Patients <50 years old w/DM and 1 Atherosclerotic RF → 2 patients
n= 50 eligible patients screened

Illustrated in figure one is the ABI scores divided into current AHA/ACC risk groups for arterial disease severity. Out of the 50 patients screened for PAD, only one patient (2%) had a normal ABI score (1.0-1.4) and was categorized in group two of the AHA/ACC risk groups. In group one, 16 patients (32%) had a borderline ABI score (0.8-1.0), group two had 23 patients (46%) with a borderline ABI score, and group three had two patients (4%) with a borderline ABI

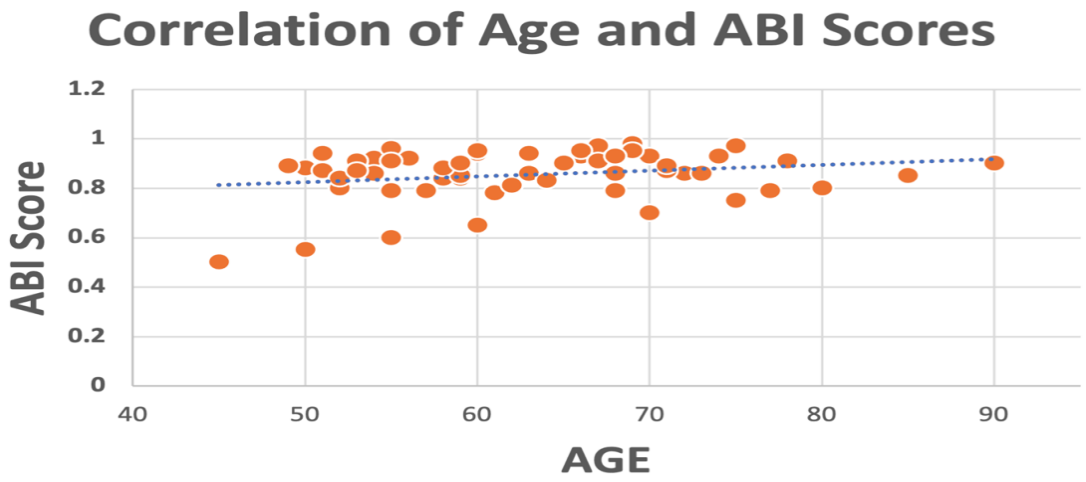
score. Finally, group one had two patients (4%) with abnormal ABI scores (0.5-0.8), group two had six patients (12%) with abnormal ABI scores, and group three had none. Seven patients scored a positive ECQ and six of these patients (12%) were categorized in risk group two, and the single remaining patient (2%) with the positive ECQ score was categorized in risk group one. The average ABI score overall was 0.88 which would indicate a borderline ABI score, with the average age being 61.9 years old.

Figure 1



Illustrated in figure two, the scatter plot represented shows a positive correlation between age and ABI score. This means that for every 10-year increase in age, ABI scores decrease anywhere between 0.1-0.2 points. For this reason, screening is imperative as patients age to prevent negative adverse outcomes such as intermittent claudication pain, limb ischemia and or limb amputation from untreated PAD.

Figure 2



The number of patients screened during this evidenced based project totaled 50 subjects, therefore a statistical analysis was performed using a fisher's exact test. The purpose of the fisher's exact test was to determine if there is an independent or random relationship between two variables, which is the ABI score and the AHA/ACC risk groups. The results of the fisher's exact test showed that the ABI and the AHA/ACC risk groups were not statistically significant based on an alpha value of 0.05 and a calculated P-value of 0.70. These results indicate that the relationship between the ABI score and the AHA/ACC risk groups are not random and dependent of one another. A future study with a screening sample of greater than 50 could utilize a chi-square test which would likely yield a more statistically significant result and stronger P-value regarding the relationship between the ABI score and the AHA/ACC risk groups.

Study Limitations

The project was designed and implemented within a 3-month period, which made it difficult to perform follow up ABI/ECQ measurements in patients whose ABI scores required aggressive management of their atherosclerotic modifiable RF. It would have been ideal to see if addressing their modifiable RF improved their previous ABI scores and claudication symptoms.

The short duration also prevented long term measurement of patient outcomes in patients who had decreased ABI scores below 0.8 which prompted additional diagnostic imaging and referral to a vascular specialist. In these long- term patients, a future study would need to consider the effect of their ABI/ECQ scores if additional treatment such as medication initiation or stent placement was indicated by the vascular specialist.

Discussion

This evidenced based project has improved provider and clinical staff knowledge regarding PAD and PAD screening. The use of current evidence from the literature coupled with current recommendations from the AHA/ACC has simplified the PAD screening process and in turn allowed implementation of an evidenced based practice protocol that can be easily incorporated in annual wellness and physical exams.

Implications for Practice and Further Research

Incorporating PAD screening in routine physical exams within a primary care setting is feasible because no additional diagnostic equipment is needed, just a good old manual blood pressure cuff and venous doppler. Since ABI and ECQ are noninvasive screening tools, clinics don't need to invest in additional diagnostic instruments such as an ultrasound machine. Future projects could include follow up ABI measurements in those whose treatment plans included aggressive management of modifiable atherosclerotic RF putting them at risk for progressive PAD, as well as long-term outcome measurements in patients whose treatment plan included referrals to a vascular specialist and additional diagnostic imaging such as a venous doppler ultrasound. Additional projects can also consider strategies regarding how an ABI and ECQ score can be incorporated into an electronic charting system to simplify clinic workflow and eliminate

the need to print out the screening forms and then having to scan them into the patient's electronic health record.

Conclusion

Screening for PAD is currently not common practice in many internal medicine and family practice clinics, even though the common demographic seen in these clinics on the daily are adult patients over the age of 50, which PAD is most prevalent in. Incorporating preventative screening in patients at risk for PAD can improve long term patient outcomes, improve quality of life, and can be implemented into clinical practice without requiring a hefty financial investment in diagnostic equipment, and would not require the entire clinical staff to undergo training for a new skill. Keeping these points in mind, screening patients for PAD can further enrich the nurse practitioner's toolset to ensure patients receive current, evidenced based, and informed preventative care.

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