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Improving the Early Detection and Management of Peripheral Artery Disease in Patients With Diabetes Within the Primary Care Setting

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IMPROVING THE EARLY DETECTION AND MANAGEMENT OF PERIPHERAL ARTERY DISEASE IN PATIENTS WITH DIABETES WITHIN THE PRIMARY CARE SETTING

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Abstract

Background. Diabetes is a significant risk factor for peripheral artery disease. Individuals with diabetes, greater than 50 years of age, having at least one other risk factor should be screened for peripheral artery disease with an ankle brachial index. **Purpose.** Improve detection and management of peripheral artery disease in persons with diabetes within primary care. **Evidence.** Individuals with diabetes and peripheral artery disease have an increased risk of adverse cardiac and limb events, impairing the patient's quality of life and causing long-term disability (Berger & Newman, 2020). **Methods.** During a 10-week period, these processes were implemented: (a) screening all patients with diabetes for peripheral artery disease risk factors; (b) conducting ankle brachial indexes for those with risk factors; (c) assessing for statin and antiplatelet medication coverage; (d) providing diet, exercise, and smoking cessation counseling; (e) referring patients with abnormal results for vascular evaluation. **Results.** 257 (83%) patients were high-risk for peripheral artery disease and needed ankle brachial index screening. A total of 23 ankle brachial indexes were completed with 3 abnormal tests requiring referrals. Of the 257 evaluated, antiplatelet therapy was utilized by 172 (67%) while statin therapy was utilized by 223 (86.7%). Education was provided to 110 of the patients. Fourteen of those were active smokers. Barriers included staffing issues and the COVID pandemic. **Implications.** Results emphasize the importance of screening and evaluating all patients with diabetes for peripheral artery disease risk factors and implementing comprehensive guidelines. For sustainment, consideration must be given to same-day ankle brachial index testing.

Keywords: ankle brachial index, peripheral artery disease, type 2 diabetes

Improving the Early Detection and Management of Peripheral Artery Disease in Patients With Diabetes Within the Primary Care Setting

Peripheral artery disease (PAD) is known to be widely underdiagnosed in the primary care setting. It is estimated that only 10% of those diagnosed with PAD endorse the classic symptom of intermittent claudication (Virani et al., 2020). The remaining individuals either have no leg pain or have various leg symptoms related to exertion that is not always enough to inhibit their physical activity (Virani et al., 2020). Its prevalence increases with age as well as possessing risk factors such as smoking, diabetes mellitus (DM) type 2, hypertension, and hypercholesterolemia (Virani et al., 2020). During the conduction of the microsystem assessment, it was noted that there was a need for a standardized approach in screening patients for PAD. Regular screening for PAD varies amongst clinical settings and is many times dependent on patients being symptomatic. Current evidence supports the use of the ankle-brachial index (ABI) as a diagnostic test for PAD. The ABI is useful in detecting PAD in both asymptomatic and symptomatic patients. This project focuses on improving the early detection and management of PAD in the diabetic population within the primary care setting through the implementation of a screening tool to identify patients at risk, screening patients determined to be a risk with a digital ABI device and utilizing evidence-based preventative measures to slow the progression of the disease in those identified to be high-risk.

Current Guidelines

The American College of Cardiology (ACC), American Heart Association (AHA), and the U.S. Preventive Services Task Force (USPSTF) outline several recommendations for the management and care of patients with PAD. The recommendations from these organizations were categorized based on the strength of the evidence in relation to patient risk and benefit

using the ACC/AHA Clinical Practice Guideline Recommendation Classification System. ABI is recommended as a diagnostic tool to establish the diagnosis of PAD when patient history or physical examination findings are suggestive of PAD (Gerhard-Herman et al., 2016). Results should be reported as abnormal (ABI ≤0.90), borderline (ABI 0.91–0.99), normal (1.00–1.40), or noncompressible (ABI >1.40). It is reasonable to obtain an ABI on patients who are noted to have increased risk factors of developing PAD but do not have history or physical examination findings suggesting PAD (Gerhard-Herman et al., 2016).

The use of aspirin 75-325 mg per day or clopidogrel 75 mg per day is recommended to reduce myocardial infarction (MI), stroke, and vascular death in patients who have symptomatic PAD. The use of antiplatelet therapy is reasonable for those who have asymptomatic PAD to reduce their risk of MI, stroke, or vascular death (Gerhard-Herman et al., 2016). The benefits of using antiplatelet therapy in those with borderline ABI is uncertain (Gerhard-Herman et al., 2016).

Other therapies that are recommended for patients who have PAD include statin therapy, antihypertensive therapy, control of DM, and cessation of smoking. The use of statin therapy is indicated for all patients with PAD (Gerhard-Herman et al., 2016). Antihypertensive therapy should be administered to those with hypertension and PAD to reduce risk of MI, stroke, heart failure, and cardiovascular death (Gerhard-Herman et al., 2016). Patients with PAD and DM should be managed by members of the healthcare team to control glucose levels and reduce complications associated with uncontrolled DM (Gerhard-Herman et al., 2016). Patients diagnosed with PAD who smoke, vape, or use any tobacco products should be advised to quit smoking, vaping, or using any form of tobacco at every visit (Gerhard-Herman et al., 2016).

Statement of the Problem

During a microsystem assessment of my clinical site, it was noted that there was not a standardized approach in screening patients for PAD, particularly among patients with diabetes. The clinic had also identified this as an issue but was in the preliminary process of establishing a protocol whereby the providers would evaluate patients for PAD, although no formal process had been approved or implemented. Earlier in 2020, the clinic purchased a digital ABI device from QuantaFlo™ as a diagnostic tool to help identify patients with decreased vascular flow secondary to PAD. However, the clinic had neither established any clinical practice guidelines for how to evaluate patients for PAD nor identified what interventions would be included in the plan of care for patients once PAD was diagnosed. My assessment of the clinical site revealed that the clinic was only using the ABI for patients presenting to the clinic with symptoms of PAD or if a patient's health insurance specifically requested the ABI testing.

The prevalence of PAD is widely underestimated in the diabetic population and can be attributed to patients being asymptomatic or symptoms being attributed to diabetic neuropathy (Berger & Newman, 2020). This delay in diagnosis of PAD increases a patient's risk of developing adverse cardiac and limb events, impairing the patient's quality of life, and causing long-term disability (Berger & Newman, 2020).

Shortly after the clinic obtained the QuantaFlo™ ABI device, the coronavirus-19 (COVID-19) pandemic caused the clinic to shift from face-to-face office visits to utilizing telemedicine as the primary healthcare delivery method for all patients, which further limited assessing ABI indexes. The urgent need to develop protocols for seeing patients via telemedicine further delayed the clinic in developing any clinical protocols for assessing ABI indexes and

identifying which interventions should be included in the treatment plan of patients who had significant altered vascular flow.

A large portion of the patient population seen at this clinic has a diagnosis of DM type 2, which has been identified as a significant risk factor for PAD. One-third of those diagnosed with PAD have DM (Berger & Newman, 2020). The AHA and ACC have identified that those individuals age 50 and older with DM who have one additional risk factor for atherosclerosis, such as a history of smoking, hyperlipidemia, or hypertension, are at an increased risk of developing PAD (Gerhard-Herman et al., 2016). In many cases, the damage done by PAD is irreversible. Establishing regular screening for PAD in patients with DM will improve the early detection of PAD and reduce the risk of stroke, MI, and amputation of the lower extremities (Virani et al., 2020). The diagnosis of PAD can be made by measuring the ABI. There are currently two methods that can be used to assess ABI. These include manually assessing ABI or using a digital ABI system.

Background and Significance

More than 170 million people worldwide have DM, and the number is growing every year (Berger & Newman, 2020). One-third of those diagnosed with PAD have DM (Berger & Newman, 2020). DM is a significant risk factor for PAD. Those with DM and PAD have an increased risk of adverse cardiac and limb events, impairing the patient's quality of life and causing long-term disability (Berger & Newman, 2020). The prevalence of PAD is widely underestimated in the diabetic population and can be attributed to patients being asymptomatic or symptoms being attributed to diabetic neuropathy (Berger & Newman, 2020). Risk factors for PAD include advanced age, smoking, hypertension, dyslipidemia, and coronary heart disease, in

addition to DM (Berger & Newman, 2020). A patient's DM duration, DM severity, sex, and race/ethnicity also play a role in the risk of PAD (Berger & Newman, 2020).

The diagnosis of PAD is made using the measurement of the ankle-brachial index. Typically, this is done manually by comparing the highest systolic blood pressure of the posterior tibial or dorsalis pedis artery in each leg divided by the highest systolic pressure of the right and left brachial artery. This method can be time-consuming and subject to user error, depending on the operator (Gajanana et al., 2019). A digital ABI system can be used as a valuable, simple, cost-effective, and reliable screening tool with high sensitivity and accuracy (Gajanana et al., 2019). A digital ABI is performed by placing the patient in a supine position with their arms and legs at the same level as their heart. The optical sensor is placed sequentially on one of the fingers on the right and left hand and on one of the toes on the right and left foot. It takes approximately 15 s to obtain a waveform on each digit. At the completion of the 60 s, a report will be generated. The ABI results are then interpreted by the provider.

Currently, the clinic uses their ABI device on an as needed basis. Most of the time, the digital ABI QuantaFlo™ is utilized to obtain an ABI on patients at the request of the patients' insurance companies. This is per the specific insurance protocols for patients with diabetes and patients without diabetes that have cardiovascular risk factors. The pandemic impacted the ability of the clinic to conduction ABI testing even when the insurance company required ABI testing since the clinic was only seeing their patients via telemedicine for several months and had only recently began seeing patients in the office on a regular basis in conjunction with the continued use of telemedicine.

The provider prescribes statins, antiplatelets, and antihypertensives to patients with diabetes at risk for PAD inconsistently. The majority of the patients who are prescribed these

medications require them for other medical conditions. Patient education specific to smoking cessation and dietary counseling is provided to patients who smoke and/or who are obese at the time they first join the clinic and initiate care. This patient education is also provided to patients newly diagnosed with diabetes. It is not regularly addressed or discussed after this initial visit unless the provider identified a specific reason to address it again. Prior to the project's implementation, these patients were receiving inconsistent preventative care and were not being screened for potential PAD risk.

Assessment

The internal medicine clinic has two locations, one on the south side of San Antonio and the other in Somerset, Texas. Both locations serve a multiracial and multicultural population. The clinics were equipped to provide a multitude of services including routine primary care, preventative medicine, industrial examinations, general health physicals, and chronic care management. The physician is the owner and primary operator of the clinics. Staff in the clinics includes one physician, two receptionists, four medical assistants (MA), one office manager, one quality manager, and one billing clerk. The physician used a systematic approach to disease management and preventative medicine using pre-developed care plans created by the physician. The clinics see on average 20-30 patients a day between both locations. The physician allots 15-30 min per patient depending on the patient's reason for the office visit. The staff ensure that appointments are properly scheduled. Ethnicity was inconsistently documented by the clinic. If a patient did not list their ethnicity on the new patient paperwork at their first visit, then it was left blank in the patient's electronic record and was not addressed further. Based on direct clinical observation, most patients were Hispanic between the ages of 40-79 years. Males accounted for

54.5% of the population. Table 1 provides details about patient demographics from my clinical assessment.

Table 1

Patient Demographics From Clinic Assessment

Characteristics	Percentage
Age Group	
20-29 years	0.99%
30-39 years	3%
40-49 years	14%
50-59 years	21%
60-69 years	32%
70-79 years	24%
80-89 years	5%
90-99 years	0.01%
Gender	
Male	54.5%
Female	45.5%
Ethnicity	
Hispanic	72%
Black	1%
White	26%
Other	1%

The top diagnoses observed in the clinic and reported by the provider included hypertension, hyperlipidemia, and DM. These direct observations were made during my onsite assessment, as the clinic does not have the ability to pull this data within their electronic system. The physician accepts a variety of medical insurances including Health Maintenance

Organizations plans, Affordable Care Act plans, Medicare Advantage plans, Preferred Provider Organizations plans, Medicare and Medicaid, and private insurance plans.

Currently, the clinics do not have a systematic approach to screen and treat patients for PAD. Before obtaining the digital ABI machine, the clinics would perform the traditional manual ABI on patients who displayed symptoms consistent with intermittent claudication and refer them to a vascular specialist when necessary, as determined by the physician. No specific screening was done for patients with DM who presented to the clinic. Any preventative measures were initiated based on the physician's recommendation after reviewing the electronic medical record (EMR) and performing an examination.

It is difficult to track what preventative measures were initiated for patients with DM who were identified as being at risk for PAD because the clinic does not have a way to extract this type of data in a reliable and consistent manner. For this reason, the use of a pre-developed plan of care is essential in ensuring that all patients receive standardized care that can be easily followed and monitored. The process created for this project ensures that screening, management, risk reduction, and referrals are all addressed as part of the pre-developed plan of care.

During the microsystem assessment, it was noted that there was a need for a standardized approach in screening patients for PAD and providing preventative measures to reduce patients' risk of developing PAD complications. Any delay in diagnosis of PAD increases patients' risk of developing a MI, stroke, and/or vascular death (Gerhard-Herman et al., 2016). The clinic provided evidence-based interventions to their patients with diabetes including the initiation of antiplatelet therapy, statin therapy, diet counseling, exercise counseling, and smoking cessation counseling for those patients identified at risk for PAD, but these measures were not done

regularly, consistently, and varied from patient-to-patient dependent on their insurance coverage, the patient's receptiveness to treatment, and the patient's regularity of follow up care. No specific process was in place prior to the project's implementation to ensure that patients with DM were receiving regular screening for PAD. Those patients who were currently receiving regular ABI screenings were patients with WellMed coverage. WellMed requires regular ABI screening as part of its wellness protocols every 3 years for those at risk for PAD or peripheral vascular disease (PVD) that have not yet been diagnosed with PAD or PVD. I determined that the clinics had the capability to conduct diagnostic testing for PAD using the ABI index but lacked uniformity in implementing current clinical practice guidelines. It was interesting to note that most of the MAs had a basic understanding of the QuantaFlo^{TM} device, but the MAs identified the need for a refresher course when asked about their comfort level using the equipment and their knowledge related to performing the procedure.

Organization's Readiness for Change

The physician and a majority of the clinic staff expressed a readiness for change in implementing a routine screening process for PAD in patients with DM, assessing ABI for patients identified to be at risk for PAD, and implementing risk reduction interventions. Some of the MAs expressed their discomfort with handling feet which could have impacted their level of cooperation and consistency in implementing the protocols. This was of particular importance to the project's success as the MAs played a pivotal role in ensuring that all interventions were carried out from the time the patients checked-in for the office visits until the patients checked out with the receptionist. Despite the MAs' initial hesitation, they were willing to implement the clinical practice guidelines that were developed for this project. The physician, who is the primary driver of change for the clinic, expressed his willingness to participate in the project and

showed interest in adopting the proposed interventions as part of the pre-developed care plan for those patients with DM who are at risk for PAD. The physician's participation in the project also allowed him to provide valuable feedback to the sustainability of the project and its effect on patient outcomes. The rest of the support staff including the office manager and the quality manager all expressed an interest in the project and provided their support throughout the development and implementation of the project. The physician and staff were well aware of the implications this project played related to patient outcomes. Their dedication and devotion to their patients inspired them to do their part to better the lives of others. A letter of support for implementing this project was obtained from my clinic mentor who also serves as the provider for the clinic (Appendix A).

Stakeholders and Stakeholders Engagement

The quality manager meets with various insurance providers quarterly to review and discuss quality metrics either virtually or by teleconference. Depending on the provider, the metrics discussed include utilization of statins, aspirin, angiotensin converting enzyme (ACE) inhibitors, diabetes control based on patients' hemoglobin A1C, and the completion of ABI testing. Interventions to improve each metric are occasionally discussed during these meetings. Reports can be regularly generated and printed to track the clinic's progress. The metrics are tied directly to the clinic's reimbursement and performance rating. Therefore, there is a financial incentive for the clinic to be implementing the recommended clinical guidelines for management of patients with diabetes in order to prevent complications associated with PAD.

Project Identification

Purpose

The purpose of this project is to improve the early detection and management of PAD in patients with DM within the primary care setting following the clinical practice guidelines outlined by the AHA and ACC for PAD. This included the implementation of a screening tool to identify patients at risk, the use of a digital ABI device for patients determined to be at risk of PAD, and implementation of evidence-based preventative measures to slow the progression of PAD and reduce the risk of complications associated with PAD.

Goals/Objectives

The objectives for this project were:

1. Increase the number of patients with DM screened for risk factors of PAD from 0% to 70% within 10 weeks.
2. Increase the utilization of ABI testing for patients with DM that have a risk factor for PAD from 0% to 50% in 10 weeks.
3. Increase the utilization of statins for patients with decreased ABI and elevated low-density lipids as a risk reduction strategy for PAD in patients with DM from 73% to 90% in 10 weeks.
4. Increase the utilization of antiplatelet therapy in patients with decreased ABI as a risk reduction strategy for PAD in patients with DM from 49% to 75% in 12 weeks.
5. Increase diet and exercise counseling amongst patients with a decreased ABI and DM from 0% to 75% in 10 weeks.
6. Increase the provision of smoking cessation education to patients with a decreased ABI and DM who are active smokers from 0% to 100% in 10 weeks.

7. Increase the referral of patients with DM that have an abnormal ABI > 1.4 or <0.8 to a vascular specialist from 0% to 100% within 2 weeks of testing (Stanford Medicine 25, 2020).

Anticipated Outcomes

The anticipated aims were as follows:

1. All staff members will receive education on PAD process, screening tool utilization, and ABI testing by February 5th, 2021.
2. By April 16, 2021, 100% of all patients with diabetes will be screened for PAD risk using the screening tool developed for this project.
3. By April 16, 2021, 50% of all patients with diabetes found to be at risk for developing PAD will have ABI testing completed.
4. By April 16, 2021, 100% of all patients with diabetes found to have an abnormal ABI >1.4 or <0.8 will be referred to a vascular specialist.

Summary and Strength of the Evidence

PAD is a global health issue that is associated with impaired quality of life, impaired functional capacity, and increased risk of major adverse cardiovascular and limb events. The burden associated with this disease process is only expected to increase with changing risk factor profiles and an aging population (Parvar et al., 2018). A review of the literature was completed using key search terms in the following databases: CINAHL, PubMed, Cochrane Library, and UpToDate. Keywords used to focus the search results were ABI, PAD, and type 2 diabetes. The level and strength of the evidence was scored using the Melnyk and Fineout-Overholt (2015) system. This system consists of seven levels and is based on a combination of quality, validity,

and applicability of the evidence to a specific patient environment (Melnyk & Fineout-Overholt, 2015). Table 2 provides a summary overview of the rating system.

Table 2

Level of Evidence

Level of Evidence	Study Design
I	Systematic reviews and meta-analysis of randomized controlled studies
II	Single, randomized controlled studies
III	Quasi-experimental studies and non-randomized controlled studies
IV	Cohort or case-control studies
V	Systematic review or meta-synthesis of qualitative or descriptive studies
VI	Single, qualitative or descriptive studies
VII	Expert opinion of authorities and/or reports of expert committees

The quality of the evidence was evaluated using the Johns Hopkins Nursing Evidence-Based Practice system (Dang & Dearholt, 2018). This system consists of four levels and uses a lettering system of A, A-B, B, and C to depict quality of evidence. The quality of evidence is based on a combination of study design, sample size, scientific evidenced reviewed, appropriateness of recommendations, and generalizability (Dang & Dearholt, 2018). Table 3 provides a summary of the rating system for quality of evidence.

A total of 21 articles were used for an in-depth synthesis of the literature for this project. Appendix B outlines the evidentiary table and rating of the evidence for this project. Specific guidelines for PAD management can be found through the AHA and the ACC (Gerhard-Herman, et al., 2016) as well as the American Diabetes Association (ADA) (2020). The AHA/ACC

Table 3

Quality of Evidence

Quality of Evidence	Criteria
A	High: Conclusive, consistent, sufficient, generalizable; sufficient sample size for study design; adequate control, definitive conclusions, consistent recommendations based on comprehensive literature review that includes thorough references to scientific evidence.
A-B	High-Good: Fairly conclusive, consistent, sufficient evidence. Meets some criteria from both A and B levels.
B	Good: Reasonably conclusive, consistent results, sufficient sample size for study designs; reasonably consistent recommendations based on fairly comprehensive literature review that includes references to scientific evidence. However, there may be some conflicting evidence.
C	Low: Inconclusive, inconsistent, insufficient evidence, insufficient sample size for the study design, inconsistent results, little references to scientific evidence. Conclusions cannot be drawn.

outlines in detail prevalence, incidence, risk factors, genetics, awareness, treatment, control, mortality, complications, healthcare utilization, and global burden of PAD (Virani et al., 2020). Globally, 202 million people had PAD between 2000-2010. An increase of 28.7% was seen in the low to middle income countries and 13.1% in high income countries (Virani et al., 2020). Smoking, type 2 diabetes, hypertension, and hypercholesterolemia account for the most common risk factors associated with PAD (Virani et al., 2020). The atherosclerosis risk in communities (ARIC) study revealed that PAD was higher among participants with lower household income and educational attainment. Several randomized and observational studies demonstrated that statins reduced the risk of major adverse cardiovascular events and amputation among people with PAD as outlined in the 2016 AHA/ACC Guideline on the Management of Patients with Lower Extremity Peripheral Artery Disease (Gerhard-Herman et al., 2016). As stated by the AHA/ACC, patients with PAD should receive comprehensive care to include structured exercise and lifestyle modifications. Smoking cessation is a vital component of care. Pharmacotherapy should be guideline based with a goal to reduce cardiovascular ischemic and limb-related events. Antiplatelet therapy with aspirin 75-325 mg per day alone is recommended to reduce MI, stroke, and vascular death in patients with symptomatic PAD (Gerhard-Herman et al., 2016). Limited evidence exists to support the use of antiplatelet therapy use in patients with asymptomatic PAD or in those at high risk of developing PAD. This does not rule out the possibility that aspirin could provide benefit in such patients (Gerhard-Herman et al., 2016). Statin therapy is indicated for all patients with PAD as it has been found to improve both cardiovascular and limb outcomes in patients with PAD. The heart protection study revealed that simvastatin 40 mg daily reduced the rate of first major vascular event by 22% relative to placebo (Gerhard-Herman et al., 2016).

In a multinational registry, statin use among these patients reduced 4-year adverse limb-related events compared with no statin (Gerhard-Herman et al., 2016).

PAD

PAD results from the buildup of plaque in the walls of the arteries thereby reducing blood flow to the limbs (Johns Hopkins Medicine, 2021). The reduction in blood flow decreases oxygen and nutrients available to the tissues. The resulting inflammation along with decrease in blood flow increases the likelihood that blood clots will form in the walls of the arteries leading to a reduction in the size of the blood vessels and an increase in the potential blockage of the arteries (Johns Hopkins Medicine, 2021). This prevalent atherosclerotic syndrome is increasing due to an aging population and an increased prevalence of risk factors with an estimated 200 million people effected worldwide (Berger & Ladapo, 2017). Those with PAD have a two to six times greater risk of developing cardiovascular and cerebrovascular events compared to those in the general population of the same age (Parvar et al., 2018). Goals of PAD treatment include reducing modifiable risk factors and prevention of cardiovascular events followed by guideline directed therapy that revolves around cardioprotective pharmacotherapies and lifestyle counseling for healthy behaviors. Studies have shown that the use of well proven cardioprotective medication therapies for secondary prevention in PAD patients lags significantly behind similar treatments for coronary artery disease (Berger & Ladapo, 2017). This is surprising as PAD is a coronary artery disease equivalent.

PAD in Patients With DM

More than 170 million people worldwide have DM and the number is growing every year (Berger & Newman, 2020). DM is a significant risk factor for developing PAD. Patients diagnosed with DM and PAD have an increased risk of adverse cardiac and limb events such as

MI, stroke, or vascular death that can impair the patient's quality of life and cause long-term disability (Berger & Newman, 2020). It is interesting to note that only one-third of those diagnosed with PAD have DM (Berger & Newman, 2020). Many healthcare providers believe that the prevalence of PAD in patients with DM is under reported because numerous patients with DM may have no symptoms of PAD and therefore are not screened for PAD or symptoms were attributed to other causes rather than PAD. Berger and Newman (2020) support this notion by stating that the prevalence of PAD is widely underestimated in patients with DM and can be attributed to patients being asymptomatic or with symptoms being attributed to diabetic neuropathy. The underlying metabolic abnormalities found in patients with DM, "enhance vascular inflammation, endothelial dysfunction, vasoconstriction, platelet activation, and thrombotic risk, processes important to the pathogenesis of PAD among patients with DM" (Berger & Newman, 2020, para. 17). The duration of a patients' DM, severity of the DM, and race/ethnicity of the patient also play a role in increasing the risk of PAD risk. African Americans and Hispanics with DM are known to "have a higher prevalence of PAD compared to non-Hispanic whites" (Berger & Newman, 2020, para.13).

The United Kingdom Prospective Diabetes Study revealed that each 1% increase in glycated hemoglobin (HbA1C) was associated with a 28% increase in incidence of PAD (Parvar et al., 2018). Those with PAD and diabetes are more likely to develop worsening lower extremity function, arterial thrombosis, and ischemic ulceration compared to those with PAD alone (Parvar et al., 2018). The pathophysiologic process of diabetes has contributed to a 5-to-10-fold increase in the likelihood of a major lower limb amputation (Parvar et al., 2018). A study found that 83% of those older than 70 years of age or those between 50-69 years of age with a known history of diabetes or smoking with a previous diagnosis of PAD were unable to recognize the diagnosis.

Of these, only half of their physicians were even aware of the diagnosis of PAD (Virani et al., 2020).

Screening for PAD

There is limited evidence on methods for screening patients for PAD. Per the AHA/ACC 2016 clinical practice guidelines, evaluating patients for PAD begins with a obtaining a complete health history, reviewing symptoms, and performing a physical examination. Patients at an increased risk of developing PAD include those greater than 50 years of age with risk factors for atherosclerosis that may include diabetes, history of smoking, hyperlipidemia, hypertension, or family history of PAD (Gerhard-Herman et al., 2016). One study conducted in Hungary revealed that the implementation of a complex screening program at the general practitioner level makes the diagnosis of PAD easier, which can lead to earlier identification and management thus improving the patients' quality of life and life expectancy (Tóth-Vajna et al., 2019). Smoking, diabetes type 2, hypertension, and hypercholesterolemia accounted for 75% of risk associated with PAD amongst men (Virani et al., 2020).

ABI Testing

The diagnosis of PAD can be made when a patient's history reveals risk factors or symptoms of PAD and physical examination findings suggest an increased risk for PAD. The ABI has been recommended as a first line test in the diagnosis of PAD due to its validity (Gerhard-Herman et al., 2016). Measurement of resting ABI is reasonable in patients at risk for developing PAD but present without history or physical examination findings that suggest the diagnosis (Gerhard-Herman et al., 2016). Traditional ABI is determined by comparing the higher systolic blood pressure in the posterior tibial artery or the dorsalis pedis artery of each leg divided by the higher systolic blood pressure of the brachial artery in the corresponding right or

left arm. These pressures are obtained by using a sphygmomanometer and stethoscope to assess the pressures manually (John Hopkins Medicine, 2021). This method is time-consuming and subject to user error. Digital ABI on the other hand can be used as a valuable, simple, cost-effective, and reliable screening tool with high sensitivity and accuracy (Gajanana et al., 2019). The digital ABI can be conducted by anyone who has been trained to use the equipment. The patient ideally should be placed in a supine position with his/her arms and legs at the same level as his/her heart. The optical sensor should be placed sequentially on one of the fingers of the right hand and the left hand as well as on one of the toes of the right foot and the left foot. It takes approximately 15 s to obtain a waveform on each digit. At the completion of 60 s, a report is generated with the ABI results to be interpreted by the provider (Schaefer, Long, & Pollick, 2016). Vascular imaging is not necessary to diagnose PAD but can help differentiate PAD from other etiologies related to the vasculature (Neschis & Golden, 2020). Resting ABI results should be reported as either abnormal (<0.90), borderline (0.91-0.99), normal (1.00-1.40) or noncompressible (>1.40) (Gerhard-Herman et al., 2016).

Risk Factors for PAD

Risk factors for PAD include advanced age, smoking, hypertension, dyslipidemia, coronary heart disease, and DM (Berger & Newman, 2020). While there is no way to reduce the risk of PAD associated with advanced age, there are medical therapies and lifestyle behavior counseling methods that can reduce the incidence of PAD and cardiovascular events associated with PAD due to modifiable risk factors. These medical therapies and lifestyle behavior counseling methods include the use of antiplatelet medications, statins, angiotensin converting enzyme (ACE) inhibitors or angiotensin II receptor blockers (ARBs), diet counseling, exercise counseling, and smoking cessation counseling (Berger & Ladapo, 2017). Studies have

demonstrated that risk factors such as smoking, hypertension, hypercholesterolemia, and diabetes significantly increase PAD risk particularly when more than one modifiable risk factor is present (Newman et al., 2017). Smoking increases PAD occurrence by 2-6 times and increases further based on the number of cigarettes smoked daily and the number of years the individual has smoked (Tóth-Vajna et al., 2019). Patients with diabetes have 2.4 times greater risk of developing PAD and critical limb ischemia than those individuals without diabetes (Tóth-Vajna et al., 2019). Amputation is five times higher for patients who have developed PAD (Tóth-Vajna et al., 2019). Hypertension is a significant risk factor for PAD although it is more prevalent in coronary diseases (Tóth-Vajna et al., 2019). Presence of dyslipidemia was found in 55% of those with PAD.

Antiplatelet Therapy to Reduce the Risk of PAD

Antiplatelet agents are a mainstay in secondary prevention to reduce adverse cardiovascular events, yet patients with PAD are often under prescribed these agents. This can be attributed to the various clinical practice guideline recommendation available to medical providers. Two trials studied the effect of aspirin on the outcomes in patients with asymptomatic PAD. The prevention of progression of arterial disease and diabetes (POPADAD) trial enrolled patients with an ABI of less than or equal to 0.99 who had diabetes and found that there was no difference in the risk of cardiovascular events or amputation between those taking aspirin and those who were given the placebo (Hussain et al., 2018). The aspirin for asymptomatic atherosclerosis study enrolled patients with an ABI less than or equal to 0.95. An average follow up of 8.2 years revealed no significant difference between those given aspirin and those who were given the placebo. Those with an ABI less than or equal to 0.09 showed no benefit in the utilization of aspirin (Hussain et al., 2018). The antithrombotic trialists' collaboration revealed

that antiplatelet use was associated with a 23% reduction in serious vascular events (Hussain et al., 2018). A limitation of this study is that it was conducted 20 years ago and compared several types of antiplatelets in addition to aspirin. The critical leg ischaemia prevention study examined both asymptomatic and intermittent claudication randomly and found that aspirin significantly reduced the risk of cardiovascular events and limb ischemia (Hussain et al., 2018). Overall, the data regarding the use of aspirin in PAD is inconclusive and this is the reason why the U.S. Food and Drug Administration has not approved aspirin as therapy specifically for PAD (Hussain et al., 2018). However, due to the increased risk of adverse cardiovascular events in asymptomatic PAD, aspirin is a reasonable therapy particularly when another vascular bed is involved (Hussain et al., 2018). When patients have symptomatic PAD, aspirin or clopidogrel is indicated (Hussain et al., 2018).

Statin Therapy to Reduce the Risk of PAD

Current practice guidelines from multiple professional societies such as the AHA, ACC, and the European Society of Cardiology recommend statin therapy for all individuals with PAD based on studies that have evaluated coronary artery disease (Crismaru & Diaconu, 2015). The heart protection study compared oral simvastatin 40 mg daily to a placebo over an average of 5 years. Overall, statin utilization was associated with a 16% relative risk reduction in vascular events and a 20% reduction in noncoronary revascularization (Aday & Everett, 2018). This included both lower extremity arterial procedures and carotid interventions. Rates of amputations did not differ between the groups. The reduction of atherothrombosis for continued health (REACH) registry revealed a “14% relative risk reduction in a composite end point that included worsening claudication, critical limb ischemia, peripheral revascularization, and amputation at 4 years” (Aday & Everett, 2018, p.1435). Statin intensity has not yet been addressed in relation to

limb outcomes nor overall mortality benefit (Aday & Everett, 2018). Aday and Everett (2018) reported on a study that compared statin intensity for those patients who were prescribed statins to those who were not prescribed statins but who were prescribed antiplatelet agents such as aspirin. A total of 155,647 patients with PAD were followed for 5.9 years. It was noted that 28% (45,503) of these patients were not prescribed statins at the time of their diagnosis despite being at high risk. This was found to be consistent from between 2006 to 2014. Low to moderate dose statins was associated with a 17% reduction in mortality and a 19% reduction in amputation compared to the high dose statin that was associated with a 26% reduction in mortality and a 33% reduction in the risk of amputation (Aday & Everett, 2018). This study was observational and included various limitations that could have accounted for the differences in clinical outcomes. Despite these limitations, this study adds to growing literature identifying the underutilization of statin therapy in patients with PAD and speaks to the role that dose intensity plays in risk reduction.

Statins have not only shown to stabilize and regress atherosclerotic plaques but also have been found to reduce inflammation and correlate with increased survival rates, reduced risk of death, and reduced risk of MIs that lead to death especially amongst those with high inflammatory processes (Crismaru & Diaconu, 2015). Also, it was noted that there was improvement in endothelial dysfunction and reduced nitric oxide levels in association with dyslipidemia that leads to increased blood flow in areas of microcirculation (Crismaru & Diaconu, 2015).

Diet Counseling to Reduce the Risk of PAD

Diet counseling for patients with diabetes that have PAD is centered around glycemic control and a HbA1C goal of <7.0. The diabetes plate method is an easy way to put together

healthy meals that assists patients in the management of blood sugar (American Diabetes Association, 2020). This method creates optimally portioned meals that balances vegetables, protein, and carbohydrates without the need to weight or properly measure food (American Diabetes Association, 2020). All that is needed is a 9-inch plate as the standard plate size to determine appropriate portion sizes. Half of the plate is filled with non-starchy vegetables as they do not raise blood sugar levels as much as other types of food. The non-starchy vegetables provide vitamins, minerals, and fiber in the diet. Examples of these types of food include asparagus, broccoli, cauliflower, brussels sprouts, cabbage, carrots, celery, cucumbers, eggplant, mushrooms, okra, green beans, peppers, salad greens, squash, and tomatoes. One quarter of the plate is filled with lean protein foods such as fish, chicken, lean beef, soy products, and cheese. Lean proteins are low in fat making these food types a healthier choice versus proteins from animal sources that contain saturated fats which increase heart disease risk. Examples include chicken, turkey, eggs, fish, shellfish, lean beef (chuck, round, sirloin, flank, or tenderloin), lean pork (center loin chop or tenderloin), lean deli meats, cheese, and cottage cheese. The last quarter of the plate is filled with carbohydrate foods that includes grains, starchy vegetables, beans, legumes, fruit, yogurt, and milk. These types of food effect blood glucose the most. Examples of carbohydrate foods include whole grains such as brown rice, polenta, oats/oatmeal, quinoa, bread, pasta, tortillas, acorn squash, butternut squash, green peas, plantain, potato, pumpkin, sweet potato, beans, legumes, fruit, and dairy products. The final component of the meal is water or a low-calorie drink. Low calorie drink options include unsweetened tea, unsweetened coffee, sparkling water/club soda, flavored water, diet soda, or other diet drinks (American Diabetes Association, 2020).

Exercise Counseling to Reduce the Risk of PAD

The majority of patients with PAD struggle with impaired walking endurance, increasing functional decline, and physical disability (McDermott et al., 2021). Those patients with PAD and DM struggle even more. This is due to the decrease in oxygen supply to the lower extremities that leads to ischemia causing individuals to experience varying degrees of pain, tightness, and weakness. Overtime this contributes to worsening dysfunction and ultimately mobility loss (McDermott et al., 2021). Goals for these patients are centered on improving walking performance and preventing further functional decline. Activities that focus on behavioral changes whether supervised or at home are recommended as they have been shown to improve walking endurance for these patients (McDermott et al., 2021). One study revealed that patients with diabetes walked significantly shorter distances, at a slower pace, and with shorter performance scores (McDermott et al., 2021). Diabetes severity was found to have a direct correlation to a patient's functional abilities (McDermott et al., 2021). The ADA (2020) recommends that patients with diabetes should perform aerobic and resistance exercises on a regular basis. Aerobic activities should last a minimum of 10 min with an overall goal of 30 min a day or more if the patient is able (American Diabetes Association, 2020). Exercise intensity should gradually increase in both frequency and duration. The goal should be to reach 150 min a week at a moderate intensity (American Diabetes Association, 2020). The avoidance of a prolonged sedentary lifestyle can help control a person's glucose levels and many times prevent type 2 diabetes. Older adults have been shown to benefit from exercises that focus on improving range of motion, strength, and balance (American Diabetes Association, 2020).

Smoking Cessation to Reduce the Risk of PAD

Smoking is a key modifiable risk factor for all manifestations of cardiovascular disease including PAD (Ratchford & Khoury, 2020). Smoking cessation counseling is an important first step in the treatment of PAD as it is known to improve symptoms of claudication. Knowledge is key and plays a part in motivating patients to quit smoking. This is what this project strived to achieve as it has been noted that up to 80% of patients with PAD are current or former smokers (Ratchford & Khoury, 2020). Smoking should be addressed using evidenced-based pharmacologic treatment and behavioral therapy as needed (Ratchford & Khoury, 2020). The patient-centered outcomes related to treatment practices in peripheral artery disease (PORTRAIT) study enrolled 1,272 patients with PAD at 16 vascular specialty clinics (Patel et al., 2018). Active smokers made up 474 of the patients. Of the remaining patients, 660 were former smokers, and 138 were never smoked. This study revealed that most patients were likely to quit early in the treatment process and quickly relapsed. At 12 months, 72% of all patients still smoked. The predominant strategy used to help these patients quit smoking was to tell patients to stop. Less than 1 in 5 smokers were referred to a smoking cessation program and only 1 in 10 received pharmacological treatment (Patel et al., 2018). Smoking patterns were dynamic over time, with a high rate of relapse which reinforced the need for repeated and consistent support and intervention. These interventions were not addressed in this project specifically due to time and resource restraints but are recommended for future projects. A study in patients with diabetes revealed a cessation rate of 11.1% amongst those who underwent intensive smoking cessation programs within 6 months (Campagna et al.,2019). The prevalence of smoking among patients with diabetes in combination with poor glycemic control and the low success rates of patients

stopping smoking on their own supports the importance of counseling smokers with diabetes of the risks associated with smoking (Campagna et al.,2019).

Summary of the Evidence

The burden of PAD is a global health issue that has been associated with loss of life and limb that is expected to increase with the aging population. Guidelines have been outlined by the AHA and ACC to guide healthcare providers in the treatment of individuals at high risk of developing PAD and those with a known diagnosis of PAD (Virani et al., 2020). The use of pharmacotherapy is focused on the reduction of cardiovascular ischemia and limb-related events. Evidence varies amongst studies and professional organizations leaving healthcare providers to decide amongst themselves what therapies are best for their patients. There is limited research related to the long-term management of PAD. Current clinical practice guidelines rely heavily on related evidence and consensus of experts in the field. Further research is needed to determine what therapies will have a significant impact on improving morbidity and mortality rates in patients with diabetes that have PAD. Diet, exercise, and smoking cessation education are also key components to help reduce the risk of patients with diabetes from developing PAD or worsening of PAD as these factors can be modified. Primary care providers should strive to provide their patients with care that is comprehensive, and protocol driven.

Methods

Project Framework

The Plan-Do-Study-Act (PDSA) cycle was used to develop this quality improvement project. This framework is useful in the adaption of evidence-based interventions into day-to-day operations (Coury et al., 2017). The topic that was chosen for this project was chosen after a detailed needs assessment was conducted and revealed a gap in screening diabetics for PAD risk

and properly testing those patients that were identified to be at high risk. The clinic had the capabilities to screen and test these patients but had no formal processes in place prior to implementation of the project's planning state (Plan). A screening tool, diagnostic testing process, and intervention plan was created in collaboration with the clinic's MAs and provider. Once the plan was finalized the staff and provider were educated on the process and the project was implemented over a 10-week period (Do). During the implementation period, I performed weekly audits to monitor compliance and adherence to the project plan. The clinic's provider was updated regularly on the project's progress (Study) to assist in identifying any areas that needed to be adjusted or addressed. Potential barriers were identified before the project was implemented to include the prominent use of telemedicine over traditional office visits during the COVID-19 pandemic. This was done by creating two separate processes the clinic staff could follow based on the type of visit the patient had to ensure all patients had the opportunity to benefit from the project plan regardless of the visit type (Act). Even though these barriers were anticipated, it remained a challenge in meeting the expected outcomes of the project. The PDSA cycle helped uncover implementation barriers that needed to be addressed in order to ensure that this project was sustainable for the clinic over time. Recommendations were made at the completion of the 10-week implementation period to ensure future success.

Project Interventions

During a patient's regularly scheduled office visit, the MAs initiated the screening tool for any patient that had a diagnosis of DM. The screening tool can be found in appendix C. The information gathered from the screening tool included patients': (a) age, (b) gender, (c) smoking history, (d) hypercholesterolemia history, (e) hypertension history, (f) heart disease history, (g) MI history; (h) stroke history, (i) and obesity status. These health history findings helped to

identify patients at increased risk of developing PAD. The screening tool also asked about family history related to PAD, heart disease, MI, and stroke since a positive family history of any of these specific risk factors increases the risk of patients developing these diseases and subsequently PAD. The screening tool was written in English using layman terms at a 6th grade reading level. Along with the screening tool, patients received an education sheet outlining the definition of PAD and its risk factors. The education was available in English and Spanish. If a patient indicated any positive history related to the risk factors on the screening tool, this triggered the MAs to conduct a digital ABI test.

A care plan was placed on the backside of the screening tool. The MAs were responsible for documenting the date of the most recent HbA1C results, lipid panel results, comprehensive metabolic panel (CMP) results, and current blood pressure reading for patients' who were screened. This helped to ensure that a lipid panel and CMP had been drawn within the past 6 months and that a HbA1C had been drawn within the past year. This information assisted the physician in evaluating patients' DM status, risks for complications that could result in PAD, and helped ensure that an appropriate treatment plan was implemented.

Once it was determined that a digital ABI test should be performed on a patient, the MAs provided the patient with verbal information regarding the benefits and risks of having an ABI test performed and how diabetes plays a factor in increasing their risk for PAD. The patient was informed that the ABI testing would be billed to their insurance. However, if the patient's insurance did not cover the ABI testing, then the ABI testing was provided to the patient at no cost. It is interesting to note that the owner of the clinic had decided that ABI testing was essential in helping to diagnosis patients at risk for PAD and therefore any ABI testing that was not covered by insurance would be provided gratis. The patient was also provided an explanation

of the risks associated with declining any of the diagnostic testing. This was necessary for patients to make an informed decision. If the patient was having a telemedicine visit, then an appointment was made for the patient to come in to get the ABI done. If the patient was being seen in the office, then the ABI was done at that time given that it did not take very long to complete.

After the digital ABI test was completed, the results were documented in the EMR, noting if the results were normal or abnormal. Additionally, the results were added to the physician's note so he could review the results as he was seeing the patient to discuss the findings and offer a recommended treatment plan. Any patient that had an ABI result >1.4 or <0.8 was referred to a vascular specialist by the physician.

Laboratory studies were ordered by the physician after reviewing the information obtained from the care plan. Patients with DM that were diagnosed with hypertension or who had an elevated blood pressure >130/80 mmHg were evaluated for the need to add an antihypertensive medication or to adjust the dosage of their current antihypertensive medications if already prescribed. All patients with DM who identified at least one more risk factor listed on the screening tool were prescribed a low to moderate dose of atorvastatin unless a higher dose was indicated according to the USPTF's (2017) clinical practice guidelines for cardiovascular care including PAD. Similarly, all patients with DM who identified at least one more risk factor listed on the screen tool who were identified as being at high risk for PAD were placed on antiplatelet aggregation therapy such as aspirin, apixaban, or rivaroxaban by the provider as a preventive measure if the patient was not already on an antiplatelet aggregation therapy.

All patients with DM who identified at least one more risk factor listed on the screening tool were provided diet counseling during the office visit. This dietary counseling included a

handout provided by the ADA that was given to the patient to take home to review and reference as needed. The handout had a graphic of a plate of food properly divided into food groups with healthy option examples. The graphic also compared portion sizes to a patient's fist size so patients could easily measure their food without having to weigh the food or use a measuring cup. All patients with DM who identified at least one more risk factor listed on the screening tool were provided exercise counseling during their office visit. This exercise counseling included a handout provided by the ADA that addressed setting achievable goals, how to start and incorporate exercise, and how to gradually increase exercise. Any patient with DM that currently smoked was provided smoking cessation counseling during their office visit. This smoking cessation counseling included a handout provided by the ADA discussing why it is important to quit and how to do so with the help of your healthcare provider.

As previously mentioned, a care plan was included on the reverse side of the screening tool outlining all the preventative measures and risk factor management therapies that were to be used to reduce the risk of PAD in patients with DM. The MAs and/or physician placed a checkmark next to the interventions that were completed during the patient's current office visit. This helped the physician and clinic staff keep track of which treatment therapies were implemented for each patient. If a patient had a contraindication for implementing an intervention such as an allergy to a medication or if the patient refused an intervention, the MAs and/or physician documented this on the care plan. Additionally, the physician documented the completed interventions in his progress note to ensure compliance with documentation requirements and to assist in appropriate billing for the patients. The MAs documented the ABI result in the patient's chart where it could easily be found in the notes section including the date that the ABI was completed. The clinic had planned to add the ABI to a spreadsheet within one

of the available patient tabs but was unable to do so before the project implementation. At the end of each day, the screening forms and care plans were collected and placed in a folder at the nurse's station in a locked drawer. Only the clinic staff, physician, and I were able to access the locked drawer. These documents provided the clinic with the ability to track PAD screenings and interventions that were implemented for each patient but also helped with data collection for the purposes of this project. The clinic utilized both a paper and electronic charting system. A paper chart was created for each patient during each visit and included a medication list and problem list along with a progress note and any other documents utilized during the visit. The physician utilized this paper chart while talking with the patient as it provided him with easy access to their medical information. At the end of this visit, the information on the paper chart was then transferred to the electronic chart by the physician and MA. At the end of each month, the charts were filed in the clinic's locked filing cabinet and referenced if necessary. Because the clinic utilized paper charts during their day-to-day operations, the choice was made to make the project's documents on paper versus creating the documents electronically.

Progress in completing screenings, completion of ABI testing, implementation of preventative measures, and referrals to vascular specialists were evaluated weekly using data collected from the care plan to determine progress in meeting the project's outcomes and helped me to identify any issues in data collection. I provided the staff and the provider with compliance information with the project interventions each week to ensure success in implementation of the project interventions.

Potential Barriers

Potential barriers included the COVID-19 pandemic that impacted the ability to see all patients face to face since appropriate safety measures had to be maintained. This meant that

some of the visits were conducted via telemedicine. I anticipated this early on prior to the project's implementation and created a process whereby all interventions could be completed regardless of the patient having a telemedicine or a face-to-face visit. I created a process flowchart for the staff to reference as needed and posted it throughout the clinic in all the common areas for the staff.

Scheduling of last-minute appointments and rushed preparation of patient charts were a barrier to implementing this project as well. Many times, patients were squeezed into the schedule without adequate time allotted for the office visit. This also resulted in chart preparation being done quickly by the MA's depending on the amount of time they had from the time of the patient's call to the time of the patient's appointment. This was in addition to the MAs' workload that was already assigned. I ensured that the screening forms and care plans were easily accessible to the MA's and that each packet was pre-made to ensure no extra time was needed to avoid taking away from the MA's daily duties.

The lack of health insurance coverage by some patients was potentially a barrier in completing the ABI testing. However, the physician agreed to provide the ABI testing gratis if the patient had no insurance or if the patient's insurance did not cover the ABI testing.

At the beginning of the project's implementation the MA's and provider were engaged and followed the process. At that time, all patients were being seen through telemedicine, but the provider agreed to allow patients to come into the office once a week to get the ABI testing done. Scheduling patients to come in for ABI testing was difficult as many patients preferred to stay home and were not open to coming into the office because of their age and the high risk for complications if they contracted COVID-19. The COVID-19 vaccine was available at the time but was difficult to obtain and was only available to select individuals. Many patients were still

hesitant to get the vaccine until more information was disseminated to the public regarding potential side effects. One week into my project's implementation, the city was impacted by a winter storm that left most of the State of Texas without water or electricity for several days along with the streets condition being dangerous that required the clinic to close for the entire week to ensure the safety of their staff and patients. The clinic was also without electricity or water during this time. The following week the clinic's computer servers went down which presented another barrier as the staff were digging through old paper charts for patient information to use for each patient's visit. Unfortunately, many appointments had to be rescheduled. Once the computer servers were up and running, the staff picked up where they left off with the project. After a few weeks went by, I noticed that the staff were utilizing the process less and less. I brought this to the provider's attention, and he said he would talk to the staff. Another week and a half went by, and I still was not seeing the staff following the process and I met with the provider again to address my concerns and provided him with preliminary data from the project. He stated that the staff had their hands full with wellness examinations as the clinic had begun seeing patient's face-to-face more regularly and this was their current priority as several of these patients were overdue for examinations due to the pandemic. He then stated that he believed that the number of ABI tests that had been done up to this point in the project's implementation was significant for a clinic of their size. This barrier impacted the project immensely and impeded its further progress despite my efforts to encourage compliance during the implementation phase.

Ethical Considerations

It is important to keep in mind that patients who lack health insurance coverage might be unable to afford the recommended PAD screenings and preventative treatments for their chronic

illness(es). The provider needed to discuss what screenings and interventions would fit within uninsured patients' budgets and would still provide an acceptable level of care to address patients' needs. Many insurance companies also do not cover ABI testing which could delay properly diagnosing patients. If insurance companies do not cover certain diagnostics and interventions, many providers may decide against implementing these services for their patients. This could lead to not diagnosing a patient with PAD until he/she was symptomatic and needed to be referred to a specialist.

All patients have the right to refuse ABI testing or any of the risk reduction strategies that were offered to them. However, it is also the provider's responsibility to explain all the risks and benefits of these diagnostics and interventions to ensure that the patient made an informed decision about how to manage their own health.

While the clinic abided by all the Centers for Disease Control and Prevention recommendations regarding COVID-19, there was still a risk to the staff and patients when scheduling ABI testing appointments since this required face-to-face meetings. The provider was confident in the clinic's disease prevention methods and was willing to allow patients into the office to have the ABI testing done. Not all the patients who needed ABI testing were willing to assume this risk and preferred to postpone the ABI testing until they received their COVID-19 vaccinations and felt safe again. Patients were encouraged to schedule the ABI testing as soon as they feel comfortable coming to the clinic.

The University of the Incarnate Word Institutional Review Board reviewed this DNP Quality Improvement Project and deemed it as non-research. Patient data collected for the project was secured at the DNP project site with all other clinic patient information. I completed

all required Health Insurance Portability and Accountability Act (HIPAA) training before the start of the DNP project.

Results

Demographics

A total of 899 patients were seen during the 10-week project implementation period from February 8, 2021 to April 16, 2021. Of these 899 patients, 308 (34%) had DM. Males made up 59% of the population that had DM. A total of 295 (96%) of the patients with DM were screened for PAD risks with 257 (87%) patients meeting the high-risk criteria that triggered the need for ABI testing. This exceeded the first outcome goal for this project which was to increase the number of patients with DM screened for risk factors of PAD from 0% to 70% within 10 weeks.

Of the 295 patients screened, 46 (16%) had their ethnicity documented in the EMR. Results indicated that 76% were Hispanic, 20% were White, 2% were African American, and 2% fell into the other category. As previously stated, the clinic did not consistently document patient ethnicity in the EMR. The new patient packet included an area for ethnicity to be documented but if the patient left this section blank, then it was not transferred into the EMR. Table 4 provides a summary of patient demographics identified during the initial screening process.

Recommendations for future revisions to this process include requiring the clinic staff to ask patients their ethnicity during the time of the patients' visits and updating that information in the EMR. This will assist in identifying potential trends related to demographic data that can assist in addressing any potential barriers that may impede patients with diabetes from receiving the care that is recommended by the clinical practice guidelines to improve their overall outcomes and quality of life.

Table 4

Patient Demographics From Project Implementation

Characteristics	Percentage
Age Group	
30-39 years	2%
40-49 years	9.8%
50-59 years	21%
60-69 years	32.5%
70-79 years	23.7%
80-89 years	10%
90-99 years	0.5%
Gender	
Male	59%
Female	41%
Ethnicity	
Hispanic	76%
Black	2%
White	20%
Other	2%

Screening

Table 5 provides a summary of patient risk factors related to health history that were identified during the initial screening process. Hypertension, hyperlipidemia, and obesity were the most common risk factors identified in the patients with diabetes that presented to the clinic.

Table 5

Patient Risk Factors Identified During the Project Implementation

Characteristics	Percentage
Risk Factors	
Hypertension	72%
Hyperlipidemia	68%
Heart Disease	22%
Stroke	3%
Obesity	51%
Smoker	5%
Family History	
PAD	0.7%
Heart Disease	2%
Stroke	0.7%

Due to the COVID-19 pandemic, a majority of patients fell behind on their regularly scheduled laboratory tests including their HgA1C, lipid panel, and comprehensive metabolic panel (CMP). These tests are preformed regularly to monitor each patient's state of health in relationship to their diagnosis of DM and their response to their current treatment regimen. This is important as it determines a patient's individualized plan of care, which aims to ensure their health needs are being met. This can include the addition or removal of selected pharmacological therapies that assist in management of the patient's DM and PAD. Of the 295 total patients seen during the implementation period, 5% had a lipid panel within the last 6 months, 10% had a

CMP in the last 6 months, and 10% had a HgA1C in the last 6 months. The average HgA1C was 8.4 which is well above the goal of <7.0 set by the ADA.

Overall, 295 (96%) of the patients with DM were screened for PAD risks with 257 (87%) patients meeting the high-risk criteria that triggered the need for ABI testing. This exceeded the first outcome goal for this project which was to increase the number of patients with DM screened for risk factors of PAD from 0% to 70% within 10 weeks.

ABI Testing

Only 23 (9%) of the patients who met the criteria for ABI testing had the ABI testing performed. Out of these 23 patients, 3 (13%) had abnormal ABI test results which revealed one patient with mild PAD (0.6-0.89), one patient with moderate PAD (0.3-0.59), and one patient with severe PAD (0-0.29). This fell short of the second outcome for this project which was to increase the utilization of ABI testing for patients with DM that have a risk factor for PAD from 0% to 50% in 10 weeks. As previously mentioned in the ethical section of this paper, barriers that impeded on the achievement of the project's desired outcomes included the lack of participation and engagement from the clinic's staff, patient fears related to the COVID-19 pandemic, and the winter storm closing the clinic for a week and temporarily shutting down the clinic computer server.

Antiplatelet Therapy

Antiplatelet therapy was utilized by 66% of the patients who presented to the clinic with a diagnosis of diabetes. Of these, 17% of patients were prescribed the therapy after seeing the provider. This fell short of the fourth outcome to increase the utilization of antiplatelet therapy in patients with DM at an increased risk of developing PAD from 49% to 75% in 10 weeks. An allergy to an antiplatelet was documented in nine of the patients seen. Many were prescribed the

medication by the provider at a previous visit but chose not to take the medication. This was observed during the chart audits as the MAs performed medication reconciliation for each patient during their office visit. The MAs noted when patients were not taking the prescribed medications or if the patients had stopped taking the prescribed medications. Further investigation into why the patients chose not to take the medication is recommended to better understand this barrier in adherence to guideline recommendation.

Statin Therapy

Statin therapy was utilized by 87% of patients with diabetes. This fell short by 3% from meeting the third outcome to increase the utilization of statin therapy in patients with DM at an increased risk of developing PAD from 73% to 90% in 10 weeks. A statin allergy was noted in 13 of the patients with two patients who refused statin therapy despite having received education by the provider on its benefits. Further investigation into contributing factors associated with patient refusal is recommended to better understand barriers attributing to the lack of adherence to guideline recommendations is recommended. All patients have the right to refuse therapies recommended by their healthcare provider, but it is the provider's ethical responsibility to ensure that the patient has the necessary information to make an informed decision.

Diet and Exercise Counseling

Diet and exercise counseling was provided to 43% of the patient population. This fell short of the fifth outcome to increase diet and exercise counseling amongst patients with DM at an increased risk of developing PAD from 0% to 75% in 10 weeks. Most of the office visits were via telemedicine. Therefore, diet and exercise counseling was provided to most of these patients remotely as since they did not come into the office for the ABI testing. Telemedicine continued to be the clinic's primary method of patient care delivery during the project's implementation

period due to the COVID-19 pandemic, accounting for 75% of all visits. Because the education was provided primarily via telemedicine, the majority of patients did not get to receive the education handouts that were available in English and Spanish unless the patients came to the clinic to have an ABI preformed.

Smoking Cessation

Of the total population seen, 14 patients were active smokers and all of them received the smoking cessation education outlined for this project. This met the seventh outcome of increasing the provision of smoking cessation education to patients who have diabetes and are active smokers from 0% to 100% in 10 weeks. As previously outlined in the methods section, this education focused on informing the patients about the role smoking plays in increasing their risk of developing PAD and encouraging them to stop. Methods to assist in smoking cessation were discussed with the patients by the provider on a case-by-case basis.

Referral to Vascular Specialist

Out of these 23 patients, 3 (13%) had abnormal ABI test results that required referral to a vascular specialist. All 3 (100%) of these patients were referred to a vascular specialist within a 2 week period, which met the seventh outcome for this project that sought to increase the referral of patients with DM that have an abnormal ABI > 1.4 or <0.8 to a vascular specialist from 0% to 100% within 2 weeks of testing. The findings and recommended treatment plan for these three patients should be forwarded from the vascular specialist back to the provider in this clinic before these patients have their next scheduled office visit at the clinic.

Summary of Results

COVID-19 greatly affected the normal procedures for the clinic. The vast majority of the office visits were via telemedicine which required patients to schedule another in-person office

visit to complete the ABI testing. At the time that the project was implemented, the COVID-19 vaccine was not readily available to the general population. Many patients were limiting any face-to-face contact with others in order to limit their exposure to COVID-19. Additionally, Texas experienced one of the worst snowstorms in its history resulting in a Statewide power outage that effected clinic operations and the EMR system. This resulted in the clinic having to shut down for 1 week. Both events most likely contributed to not meeting the ABI testing goal. The inability to provide patients with educational materials at the time of the office visit and the limited amount of time the provider had to see patients most likely accounts for not meeting the diet and exercise counseling goals. Some progress was made in ensuring that patients with diabetes who were at risk for PAD were prescribed an antiplatelet medication and a statin as a risk reduction strategy in accordance with the clinical practice guidelines. The clinic will most likely reach the anticipated adherence goals as these interventions are cemented into the clinic's routine. The rest of the anticipated adherence goals were achieved. Table 6 provides a summary of the results obtained from this project.

Discussion

When the project's process (Appendix E) was followed by all staff members and the provider, the project implementation ran smoothly. The vast majority of the patients were receptive to the interventions and the education provided. Many of the patients verbalized their unfamiliarity with PAD and were surprised to learn that they were at risk for PAD based on their medical diagnoses and history. This most likely helped to motivated them to learn more about how to improve their lifestyles through diet and exercise and reduce their PAD risk. The importance of both antiplatelet and aspirin utilization was also discussed at length with these patients. Many verbalized their understanding regarding the important role these medications

Table 6

Outcome Summary Pre-Intervention and Post-Intervention

Intervention	Pre-Intervention	Anticipated Outcome	Post-Intervention
Staff education	0%	100%	100%
Screening form	0%	80%	96%
ABI testing	0%	50%	9%
Statin utilization	73%	90%	87%
Antiplatelet utilization	49%	75%	66%
Diet/exercise counseling	0%	80%	43%
Smoking cessation education	0%	100%	100%
Vascular referral	0%	100%	100%

played in their daily regimen while others believed these medications to be just another pill in their pillbox. Once the ABI was completed and the results were reviewed, some patients verbalized surprise about ease of ABI testing and the short amount of time it took to complete the ABI testing.

Difficulties with project implementation compliance arose when the staff were no longer following the project process flowchart (Appendix E) around week 5. The MAs were only completing the screening tool but were not following through with the rest of the project interventions. Once I identified that this was occurring, I notified the provider to discuss what could be done to get the staff back on track in implementing the project plan. The provider reinforced the importance of completing the interventions with the staff as they were essential in

helping to complete the care plan that had a direct effect on patients' long-term outcomes and helped direct the provider on the interventions that needed to be included in the patients' plans of care. Despite reinforcement by the provider, the staff continued to show a lack of participation.

I once again brought this to the attention of the provider. However, this time the provider's response was unexpected. Previously, he had expressed his full support of the project and assisted with its creation prior to implementation. Now in week 6 of implementation, the provider stated that he believed that the number of ABI's that had been completed was sufficient for the size of the clinic and stressed that the clinics current focus would revolve around the completion of patient wellness examinations which had been significantly delayed due to the COVID-19 pandemic. At this point, it was evident that the project would not meet all the expected outcomes as the provider was the driving force in directing operations of the clinic. Without his support, not much more could be done. Wellness visits are essential as they provide healthcare providers with an update on patients' overall health. The goals of this project were aimed at identifying those at risk of developing PAD which is consistent with the purpose of having wellness examinations done on an annual basis. I recommended that the PAD screenings be integrated as a component of the wellness examinations to increase future compliance with screenings and reduce the risk of life and limb events for patients with diabetes. The earlier PAD is identified, the sooner referrals can be made, intervention can be initiated, and long-term health outcomes can improve.

The strength of this project's design was that all potential variables were considered during the development of the project process flowchart (Appendix E) to include both telemedicine and face-to-face visits. The project process flowchart provided the staff and provider an easy-to-follow approach to ensure the project's success. All patient packets were pre-

assembled to ease the burden on the MAs. The packets were easily accessible to the MAs at the nurse's station. While the project added a small amount of workload on to the MA's current workload, it was not observed to have taken away from their regular duties as I noticed that the MAs continued to have time to check their social media, take personal photographs, and make personal calls. This information was relayed to the provider during our second meeting in which we discussed process flow issues.

Relationship to the Evidence

The results of the project were consistent with evidence emphasizing the underutilization of prevention and lifestyle counseling in patients with PAD. Berger and Ladapo (2017) identified that prevention and lifestyle counseling is underutilized in patients with PAD. This is concerning, since most of the patients seen during this project's implementation also had diabetes mellitus, which increases their severity risk of developing PAD. Likewise, this project supported the findings of Aday and Everett (2018) who identified that the use of statin therapy is underutilized in patients with PAD. As previously stated, patients seen during this project's implementation also had diabetes mellitus. This comorbidity not only increased the likelihood that these patients would develop PAD but also increased the likelihood that these patients would develop an underlying cardiac condition such as atherosclerosis and hypertension placing them at greater risk for a MI. This project identified that prescribing of statins and antiplatelet therapy such as aspirin was not a consistent part of the practice. Based on findings from their study, Gerhard-Herman et al. (2016) identified that despite limited evidence, aspirin therapy may reduce the risk of complications associated with PAD and statin therapy improved both cardiovascular and limb outcomes in patients with PAD. These findings support a continued efforts for the primary care practice to follow the project process flowchart (Appendix E) that

incorporates the use of antiplatelet and statin therapy. While all patients seen during the project implementation who smoked were provided smoking cessation counseling, it would be prudent to encourage patients to enroll in some type of smoking cessation program. Patel et al. (2018), identified that simply telling patients to stop smoking did not result in long term cessation of smoking. Referral to a more structure smoking cessation program that includes both behavioral and pharmacological treatment may increase the likelihood of success. Overall, this project improved the process of caring for patients with diabetes who were at risk for developing PAD. The project process flowchart addresses the main risk factors associated with PAD and includes pharmacological and lifestyle management therapies based on the most current evidence. The challenge is incorporating current clinical practice guidelines into the day-to-day practice despite the current challenges associated with the COVID-19 pandemic. Utilization of the project process flowchart will help to improve the quality of care for these high-risk patients at the primary care level.

The greatest limitation in the implementation of this project was the amount of ABI's conducted, which were much less than what was anticipated for this project making it impossible to determine the number of patients both symptomatic and asymptomatic who had PAD but were unaware of their diagnosis. Without an ABI, no formal diagnosis of PAD can be made. The low number of ABI's that were performed was due to the barriers previous described such as telemedicine office visits, inconsistent use of the project process flowchart, and the COVID-19 pandemic. These barriers were not identified in previous studies. These are areas that need further investigation to determine what strategies can be used to improve compliance in ABI testing. It is likely that if the barriers had not been present, the testing numbers might have improved significantly. Of the 257 high risk patients identified, 23 (9%) had the ABI testing

performed. Out of these 23 patients, 3 (13%) had abnormal ABI test results. This is in contrast to Tóth-Vajna et al. (2019) who found that 23% of their patient population to have abnormal results. The low number of actual ABI test performed during this project's implementation limits the ability to compare outcomes with those found by Tóth-Vajna et al. (2019). Once consistent implementation of the project process flowchart occurs in this primary care setting, a comparison between patient outcomes for this practice and the literature can more reliably be established.

As previously mentioned, the patients with diabetes seen in this clinic often had hypertension (72%), hyperlipidemia (68%), and obesity (51%). This is not an uncommon finding. Tóth-Vajna et al. (2019) noted that the health professionals' follow-up study had similar findings that included the identification of hypertension (77%), hyperlipidemia (55%), diabetes (33%), and active smokers (24%) as frequent vascular risk factors.

Active smokers made up 5% of the patients with diabetes in this practice that were found to be at high risk of developing PAD. This was significantly less than the 24% found by Tóth-Vajna et al. (2019). Tóth-Vajna et al. (2019) identified that major amputations in Hungary were triple the international average due to the late recognition of PAD. Observational studies found amputations, myocardial infarctions, and death risk to be significantly greater among those who continue to smoke with a known diagnosis of PAD in comparison to those who stopped smoking (Virani et al.,2020). The added comorbidity of DM increases the risk that patients seen in this practice who smoke will develop PAD or an associated limb event.

Project results revealed 68% of patients to have hyperlipidemia while an observational study conducted in several general practice offices revealed 55% of the population to have hyperlipidemia (Toth-Vajna et al., 2019). This may be attributed to a higher incidence of uncontrolled DM in this area. Statin therapy is known to stabilize and regress atherosclerotic

plaques, but statin therapy has also been found to reduce inflammation and correlates with increased survival rates and reduced risk of death (Crismaru & Diaconu, 2015). It has also been noted to improve endothelial dysfunction and reduced nitric oxide levels in association with hyperlipidemia that leads to increased blood flow in areas of microcirculation (Crismaru & Diaconu, 2015). Statins were utilized by 87% of high-risk patients in this project post-implementation compared to the 73% pre-implementation. This was more than the 62.2% that was found to be taking a statin in the REACH registry (Parvar et al.,2018).

While there is no way to reduce the risk of PAD associated with advanced age, there are medical therapies and lifestyle counseling methods that can reduce the incidence of PAD and cardiovascular events associated with PAD due to modifiable risk factors. Risk factors such as smoking, hypertension, hypercholesterolemia, and DM significantly increase PAD risk particularly when more than one modifiable risk factor is present (Newman et al., 2017). Smoking increases PAD occurrence by 2-6 times and further increases based on the number of cigarettes smoked daily and the number of years the individual has smoked (Tóth-Vajna et al., 2019). Patients with diabetes have 2.4 times greater risk of developing PAD and critical limb ischemia than those individuals without diabetes (Tóth-Vajna et al., 2019). Amputation is five times higher for patients who have developed PAD (Tóth-Vajna et al., 2019). Further evaluation over time is needed to draw specific conclusions about this project's effect on long term patient outcomes.

Limitations

There were several limitations to implementation of this project. One of the biggest obstacles centered around the primary use of telemedicine instead of face-to-face office visits and the lack of opportunities to obtain ABI testing while patients were being seen by the

provider. This resulted in patients needing to schedule multiple visits with the physician to obtain the ABI testing and to ensure that all the interventions were addressed. This caused confusion for some patients and resulted delays in diagnosing PAD in patients identified to be at high risk and missed opportunities to implement preventative PAD interventions.

The EMR was also a limitation as the current EMR system was not able to extract reliable data reports and lacked the capability to add the project's interventions into a spreadsheet that could be tracked over time. This resulted in staff having to locate project outcome data in patients' paper charts and increased the likelihood of paper documents being lost. A more advanced EMR system would allow for provider alerts and intervention reminders which would prompt staff to complete the interventions and allow for real time data collection instead of manual data collection which was a time consuming and tedious task. However, new EMR systems can be expensive and thus cost prohibitive for the clinic.

Unexpected barriers to implementing this project included the power outages that occurred during a winter storm that effected the Texas statewide electrical grid resulting in the closure of the clinic for a week and computer server disturbances. This was compounded by the COVID-19 pandemic that resulted in patients being hesitant to come into the office to obtain their ABI's due to a fear of contracting the COVID-19 virus if they left their homes. During implementation of this project the COVID-19 vaccine had just become available to selected pre-identified patient groups based on age, health issues, and profession type. Many patients were also hesitant to receive the vaccine as it was still very new and was not fully FDA approved. These barriers were out of the anyone's control. These barriers directly impacted the project's implementation and subsequent results. Without these specific barriers the project might have been able to be more fully implemented.

Recommendations

Project recommendations include the screening of patients with diabetes for PAD risk at face-to-face office visits to ensure the completion of ABI testing. The telemedicine process will work if staff follow the project process flowchart and patients make ABI testing appointments with the receptionist before concluding their telemedicine visit. Any deviations from the project process flowchart increase the likelihood of a process breakdown resulting in missed opportunities to identify, test, and diagnose patients at risk of developing or having PAD and implementing appropriate interventions to reduce the risk of complications associated with PAD. The staff should be closely monitored for compliance in following the project process flowchart and be held accountable if it is found that they are not following the flowchart. Compliance with the project process flowchart should be rewarded since staff recognition can ensure continued compliance both those staff members that have been recognized and encourage the other staff members to improve their performance. The movement of PAD screenings to the annual wellness visit would assist in ensuring that ABIs are routinely conducted for patients at risk for PAD. Various other screenings are performed during these wellness visits which makes this the prime time to implement PAD screening and ABI testing. This will help ensure compliance with the project process flowchart and reinforces the reason for the wellness visit which is primarily prevention focused. Further investigation into the reasons why patients refused antiplatelet and statin therapy is also recommended to better understand the barriers to the adherence of these specific guideline recommendations.

Primary care providers, insurers, and other members of the healthcare team need to do a better job of educating both patients and their fellow colleagues on the importance of prevention and pharmacotherapy to reduce the effects of PAD on both life and limb of patients with diabetes

and PAD. A combination of guideline recommended therapies to include cardiovascular preventative medications such as antiplatelets and statins along with secondary prevention and lifestyle counseling (diet/exercise counseling and smoking cessation) have proven time and time to improve quality of life and outcomes, yet they remain to be underutilized. Patient outcome should always be at the forefront and more needs to be done to ensure that these high-risk patients are getting the care they deserve.

Sustainability

Sustainability can be maintained by anticipating potential barriers and implementing strategies to mitigate the barriers. For example, the likely prevalence of telemedicine visits over face-to-face visits was anticipated in the planning stage. Because of this, time was taken to outline a process that allowed for interventions to be achieved regardless of the type of patient visit. However, the unexpected finding that patients did not want to participate in any face-to-face office visits due to COVID-19 despite proper precautions being taken was an unanticipated barrier. Moving the ABI testing to the wellness examination increases the likelihood that the testing will be completed. The staff and provider were also updated regularly on how they were performing in order to ensure transparency, open communication, and accountability. Despite these efforts, staff were not held accountable for their performance which lead to a lack of participation by the staff. While the project leader serves as a champion for the change process, success of any project is dependent on the buy in, and support of the staff involved in implementing the plan. This was a lesson learned and something that should be carefully considered when developing a plan. This may require more face-to-face interaction with staff, longer implementation timeline, or other various strategies to help engage those on the frontlines to implement plans that can improve patient outcomes. One suggestion for future projects would

be to provide staff incentives those who actively participate in implementing the plan and help to reach the goals for the projects. This will contribute to staff empowerment and will encourage goal-oriented behaviors. Weekly goals should be set and readily available for staff to refer to in common areas along with current compliance information. This serves as a reminder to staff to keep their eye on the goals. This strategy was not implemented in this project as the clinic was small and the decision was made to provide weekly in person project updates.

The early identification and prevention of PAD complications can decrease costs for the provider since less resources would be utilized in managing these patients with complicated diseases processes over the long term. The time saved from having to address complications that might otherwise have developed could be used to focus more on the management of patients' diabetes and other comorbidities. More time could also be devoted to improving the billing of preventative services to ensure the clinic is being properly reimbursed for the services they are providing to their patients.

Implications for Practice

Results from this project revealed that 13% of those who had an ABI test had an abnormal result that required a referral to a vascular specialist for further evaluation. Though the sample size was small, this finding supports the utilization of ABI testing in the primary care setting to identify the presence of PAD and ensure its proper treatment. The primary care provider can help minimize complications associated with PAD by addressing risk factors. Modifying risk factors for PAD can reduce patients' risks of having a stroke, MI, or amputation of the lower extremities (Virani et al., 2020). It is important to keep in mind that many of the complications that occur with PAD develop over a period of time. Measuring the success of a project such as this one will take time. However, it is essential to monitor patient outcomes in

order to address areas in practice that may need specific attention in order to ensure the safety and well-being of patients.

Clinical practice guidelines serve as a tool to help providers offer the best care possible based on the best evidence at the time. Professional organizations help to develop these practice recommendations based on the evidence and the collective expertise of their members. This peer review process helps to ensure consensus on the best approach to caring for a specific patient population. It is the expectation of the doctoral-prepared nurse practitioner to remain informed of the most current evidence and practice guidelines and help translate this information into practice to ensure the best patient outcomes.

Doctorate prepared advanced practice registered nurses have the knowledge, skill, and experience to conduct quality improvement projects within healthcare systems that are patient centered and geared to improve patient outcomes. This is done through the conduction of a multistep system assessment. The information collected provides insight and assists in the implementation of processes that are evidence-based and specific to a targeted population. This project reinforces the importance of conducting a microsystem assessment, staff education, assessment of barriers, facilitators, and the development of practice protocols for the care of patients with DM at risk for developing PAD in the primary care setting.

Conclusion

Diabetes is a significant risk factor for PAD. Those with DM and PAD have an increased risk of adverse cardiac and limb events, impairing the patient's quality of life and causing long-term disability (Berger & Newman, 2020). Despite these significant and life-threatening risks, PAD remains underdiagnosed in the primary care setting. The evidence has identified that there is an underutilization of prevention and lifestyle counseling in patients at risk for PAD. This can

be easily addressed through the implementation of PAD screening, ABI testing, statin and antiplatelet utilization, diet and exercise counseling, and smoking cessation education. Prevention is a key component of primary care, and more time should be invested in implementing these strategies in the primary care setting in order to reduce the incidence of disease associated patient outcomes. Even though the results from this project's implementation were not immediately seen for each intervention, the evidence support their continued use with the benefits outweighing any risks. These interventions are easy to implement and are worth considering as early identification and treatment of PAD in patients with DM and has the ability to impact patient health, well-being, and longevity of these patients' lives, a life that they only get to live once. This along with time is simply invaluable.

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Appendix A:

Letter of Support

November 24, 2020

Dear Dr. Rocha,

This letter serves as a letter of support between Name of Medical Clinic and the University of the Incarnate Word (UIW) Ila Faye Miller School of Nursing, Doctor of Nursing Practice (DNP) program in support of Julyssa A. Rodriguez implementing her proposed DNP project at your clinic. This project aims to improve the early detection and management of peripheral artery disease in the diabetic population within the internal medicine clinic. This project is consistent with the mission of Name of Medical Clinic by helping to improve the early detection and management of chronic disease and overall improving patient care and outcomes.

As an organization you have demonstrated your commitment to improving patient care while helping mold future medical practitioners. We appreciate your commitment and partnership with the UIW's DNP students both as a preceptor and mentor. This project will be implemented during the Spring 2021 semester. Dr. Michael D. Moon will serve as the UIW Faculty project advisor and is available to answer any questions that you may have regarding the project requirements. He can be reached at mobile number . UIW is delighted to be collaborating with you to maximize the care that your clinic provides to the residents of San Antonio.

We look forward to a productive partnership between Name of Medical Clinic and UIW.

11/24/20
Mentor Signature/Date

Dr. Guillermo Rocha MD, PA
Print Mentor Name

Appendix B:

Evidentiary Table for Summary of Evidence

Reference	Purpose	Setting	Findings/Implications	Quality of Evidence	Level of Evidence
Aday & Everett (2018).	Purpose: Address some of these key outstanding questions regarding the efficacy of statin therapy in patients at risk of developing PAD.	Design: Observational Setting: 155,647	Findings: Statin therapy is underutilized in PAD patients. Strong, intensity-dependent association between statin therapy and both amputation and mortality among individuals with incident PAD is of considerable clinical importance. Implications: The utilization of statin therapy in patients with PAD can reduce rates of amputation and mortality. This does not only benefit patients but physicians.	III	B
American Diabetes Association (2020).	Purpose: Provide clinical guidelines to patients with diabetes.	Design: N/A Setting: N/A	Findings: The diabetic my plate method can be utilized to educate and assist patients in following a diet that assists in glycemic control. Implications: The utilization of the diabetic my plate method will improve glycemic control amongst patients with diabetes and minimize the occurrence of adverse events secondary to diabetes.	VII	A
Berger & Ladapo. (2017).	Purpose: Evaluate trends in both medical and lifestyle counseling for patients diagnosed with PAD.	Design: N/A Sample: N/A	Findings: Secondary prevention and lifestyle counseling are underutilized. Patients with peripheral vascular disease are at risk for impaired quality of life and significant morbidity and mortality. The use of medical therapy and lifestyle counseling reduces the incidence of cardiovascular events in PAD. Implications: The utilization of secondary prevention in patients with PAD can improve patient outcomes and quality of life.	VII	B
Berger & Newman (2020).	Purpose: Provide an overview of PAD in patients with diabetes.	Design: N/A Setting: N/A	Findings: Diabetes is a significant risk factor for PAD that increases a patient's risk of developing adverse cardiac and limb events. Implications: N/A	VII	B

Reference	Purpose	Setting	Findings/Implications	Quality of Evidence	Level of Evidence
Campagna et al., (2019).	Purpose: Discuses the relationship between diabetes and smoking to include complications and smoking cessation.	Design: N/A Setting: N/A	Findings: The interaction between smoking and DM is complex. Smoking increases risk of cardiovascular and macrovascular complications. Implications: N/A	VII	B
Crismaru & Diaconu (2015).	Purpose: Provide guideline recommendations.	Design: Clinical guidelines Setting: N/A	Findings: The European Society of Cardiology recommend statin treatment for all patients with PAD. Benefits of treatment outweigh the risks as PAD places patients in a high cardiovascular risk category. Implications: Statins are beneficial in preventing cardiovascular events in these patients and, due to their pleiotropic effects, can also increase the functional capacity and lower the risk of adverse limb outcome.	VII	A
Gajanana et al. (2019).	Purpose: Provide an objective analysis of the relationship between digital ABI and peripheral angiographic data.	Design: Retrospective Sample: 51 patients with risk factors and/or symptoms of PAD	Findings: The FloChec digital ABI system can be used as a valuable, simple, cost-effective, and reliable screening tool with high sensitivity and accuracy. Implications*:* These results support the use of digital ABI systems being utilized in the primary care setting as a reliable screening tool versus the doppler. The earlier the diagnosis of PAD is made the better the outcomes for the patient	VII	A
Gerhard-Herman et al. (2016).	Purpose: Provide clinical practice guidelines.	Design: Clinical practice guideline Setting: N/A	Findings: Reviews preventative measures such as physical activity, diet, smoking cessation, and stresses the importance of managing diabetes as these interventions slow the progression of the disease and at times reverse symptoms. Implications: The AHA/ACC recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation.	VI	A

Reference	Purpose	Setting	Findings/Implications	Quality of Evidence	Level of Evidence
Hussain et al. (2018).	Purpose: Summarize the current available evidence for the safety and efficacy of various antithrombotic agents in PAD and discuss how to integrate this emerging evidence into actual clinical practice.	Design: RCT's Setting: 16 RCT's	Findings: Evidenced-based approach to PAD patients is essential to achieve optimal outcomes, weighing cardiovascular and limb benefits against bleeding risks. Implications: The use of antithrombotic therapy can prevent adverse cardiovascular events in patients with PAD.	I	A
John Hopkins Medicine. (2021)	Purpose: Discusses the key points of PVD and PAD.	Design: N/A Setting: N/A	Findings: Peripheral vascular disease can affect various blood vessels. The goal of treatment is to restore blood flow and prevent disease progression with the assistance of various therapies. Implications: N/A	VII	B
McDermott Spring, & Tian (2021).	Purpose: Determine whether low-intensity home-based walking exercise at a comfortable pace significantly improves walking ability in people with PAD vs high-intensity home-based walking exercise vs a nonexercised control group.	Design: RCT Setting: 305 participants	Findings: Low-intensity exercise was significantly less effective than high-intensity exercise and was not significantly different from the control. Implications: Supervised high-intensity walking exercise that induces ischemic leg symptoms is the first-line therapy for people with lower-extremity peripheral artery disease (PAD), but adherence is poor.	I	B
Neschis & Golden. (2020).	Purpose: Provide an overview of the clinical features and diagnosis of PAD.	Design: N/A Setting: N/A	Findings: PAD is a growing problem among the aging population and its risk factors are like those of coronary atherosclerosis. Implications: N/A	VII	B

Reference	Purpose	Setting	Findings/Implications	Quality of Evidence	Level of Evidence
Newman et al. (2017).	Purpose: Identified diabetes mellitus as a coronary heart disease risk equivalent for PAD.	Design: Cross-sectional analysis Setting: 3.5 million self-referred participants	Findings: Diabetes was a coronary heart disease equivalent for PAD and coronary artery stenosis. Implications: Screening and prevention of peripheral vascular disease is recommended for patients with diabetes as it has shown to improve outcomes.	VII	B
Parvar et al. (2017).	Purpose: Reviews evidence for the noninvasive management of PAD and provides clinical recommendations.	Design: Comprehensive literature review Setting: N/A	Findings: Medical and lifestyle management of patients with PAD should focus on improving outcomes and reducing cardiovascular events to include smoking cessation, exercise therapy, antiplatelet therapy, anticoagulant therapy, antihypertensive therapy, lipid-lowering therapy, and glycemic control in patients with diabetes. Implications: A multifactorial approach that is methodical to each risk factor that accounts for all potential contributing factors is recommended for the treatment of PAD. Decision making should be specific to each patient.	VII	A
Patel et al. (2018).	Purpose: Examine smoking rates and smoking cessation interventions offered to patients with PAD and fill knowledge gaps.	Design: Multicenter registry Setting: 1272 patients	Findings: Patients appear to be most likely to quit early in their treatment course, but many quickly relapse and 72% of all patients smoking at baseline are still smoking at 12 months. Better strategies are needed to provide continuous cessation support. Implications: A better effort needs to be made to offer ongoing evidence-based smoking cessation support in patients with PAD.	III	A
Ratchford & Khoury (2020).	Purpose: Discuss smoking cessation pathway outlined by the ACC.	Design: Clinical guideline Setting: N/A	Findings: The 5 A's framework can assist with smoking cessation counseling to prevent and treat all forms of CVD. Implications: Smoking is a modifiable risk factor that can be treated using the decision pathway set by the ACC to reduce the risk of cardiovascular events.	VII	A

Reference	Purpose	Setting	Findings/Implications	Quality of Evidence	Level of Evidence
Schaefer, Long, & Pollick (2016).	Purpose: Compare the accuracy of the QuantaFlo to ABI, using primarily duplex ultrasound to confirm the presence or absence of PAD.	Design: Cohort study Sample: 180 patients and 360 limbs	Findings: The QuantaFlo can detect PAD with greater accuracy then the traditional ABI. Implications: The QuantaFlo is highly accurate and has the potential to identify peripheral vascular disease in conjunction with physical exam and patient history. The use of this tool can improve the in-office diagnosis of PAD and encourage early identification.	IV	B
Stanford Medicine 25. (2020).	Purpose: Explain ankle brachial index measurement, interpretation, and management recommendations.	Design: N/A Setting: N/A	Findings: ABI has been shown to predict mortality and adverse cardiovascular events independent of traditional CV risk factors and is recommended in every smoker over 50 years old, every diabetic over 50, and all patients over 70. Implications: The correct ABI measurement can assist in the reliable diagnosis of PAD and ensure early identification of the disease process.	VII	A
Tóth-Vajna et al. (2019).	Purpose: Improve the efficiency of primary health care screening in PAD and reduce the extremely high domestic amputation ratio.	Design: Observational Sample: 816	Findings: Peripheral artery disease is diagnosed late in the primary care setting. Screening with ABI has a sensitivity and specificity between 79%-96%. Implications: The early detection of PAD in primary care significantly improves patient quality of life and life expectancy.	VI	B
U.S. Preventive Services Task Force. (2017).	Purpose: Clinical practice guideline.	Design: Clinical practice guideline Setting: N/A	Findings: The USPSF concludes that the current evidence is insufficient to assess the balance of benefits and harms of screening for PAD and CVD risk with the ankle-brachial index in asymptomatic adults. Implications: The USPSF recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation.	VII	A
Virani et al. (2020).	Purpose: Provide clinical practice guidelines.	Design: Clinical practice guidelines Setting: N/A	Findings: Guidelines address peripheral artery disease and are a reference utilized by healthcare providers to care for patients at risk based on the most recent evidence provided by this organization. Implications: The AHA recognizes that clinical decisions involve more considerations than evidence alone. Clinicians should understand the evidence but individualize decision making to the specific patient or situation.	VI	A

Appendix C:

Screening Tool

Rocha Medical Clinic

Peripheral Artery Disease Risk Screenig Diabetic Patients

Age of patient: 20-29, 30-39, 40-49, 50-59, 60-69, 70-79, 80-89, 90-99

Sex of patient: Male Female

Ethnicity: African American Asian Hawaiian Hispanic White

RISK FACTORS	YES	NO
>50 years of age		
Diagnosis of high cholesterol		
Current smoker		
Diagnosis of high blood pressure		
Diagnosis of heart disease		
History of heart disease		
History of myocardial infarction (heart attack)		
History of Stroke		
Obese (BMI>30)		
FAMILY HISTORY		
Peripheral artery disease		
Heart Disease		
Myocardial infarction (heart attack)		
Stroke		
Total:	/13	/13

Management Post Screen:

Management: combination of ( ) risk > 2, ( ) DM, ( ) age over 50

Positive screen: Outcome: ( ) refer to vascular, ( ) schedule ABI, ( ) Being seen by vascular

Patient Name:	DOB:	Insurance:

RMC: ( ) 3727 Roosevel Ave, Roosevelt; ( ) 19575 K Street, Somerset

Appendix D:

Care Plan

Peripheral Artery Disease – PAD Care Plan

Name: _____ **DOB:** _____ **ID:** _____ **Date:** _____

Risk Factors: ( ) Diabetes, ( ) Hypertension, ( ) Coronary Artery Disease, ( ) Smoking, ( ) Hyperlipidemia, ( ) Atherosclerosis, ( ) Peripheral Vascular Disease, ( ) Myocardial infarction- heart attack, ( ) Claudication, ( ) Decreased pulses, ( ) Leg ulcers, ( ) Ischemic changes legs, ( ) Age, ( ) AAA, ( ) Kidney disease- CKD, ( ) Stroke, ( ) Previous Amputation

Risk factor score: _____ of 12 (x/12)

Findings: Left leg: **ABI Index:** _____ Interpretation: _____

Right leg: **ABI Index:** _____ Interpretation: _____

Interpretation: ( ) Non compressible >/– 1.30, ( ) Normal 1.0 to 1.29, ( ) Borderline (equivocal) 0.91 – 0.99, ( ) Mild to Moderate 0.41 to 0.90, ( ) Severe PAD 0.00 to 0.4

AFP: ( ) Normal 1.0-1.3, Borderline 0.9-1.0 Mild 0.7-0.9, Moderate 0.4 0.7, Severe < 0.4

Diagnoses: ( ) I70.20 Atherosclerosis unsp, ( ) I70.21 Atherosclerosis w/claudication, ( ) I70.22 Atheros w/rest pain, ( ) I70.26 Atheros w/gangrene (1=R, 2=L, 3=bilat, 9=unsp extremity; ( ) I70.92 chronic total occlusion extremity ( ) I70.30-I70.79 Atherosclerosis bypass graft extremity

Management: Life style changes: ( ) diet, ( ) exercise, ( ) smoking cessation

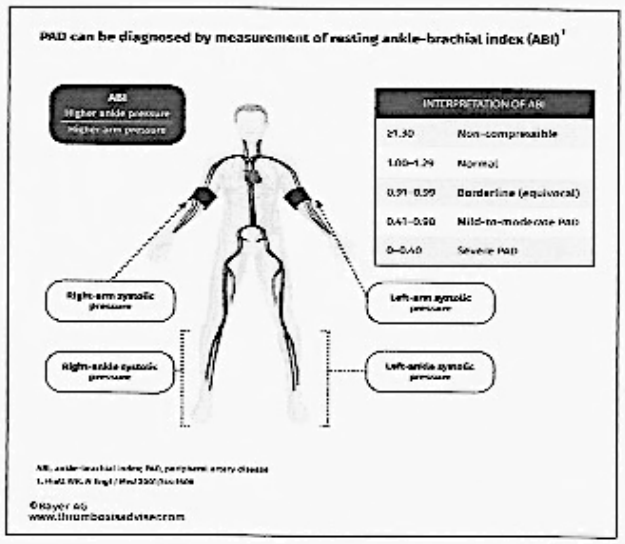
Medications: ( ) Aspirin, ( ) Statin (atorvastatin, crestor, etc), ( ) Ace Inh, ( ) Persantine (dipyridamole), ( ) Coumadin- Warfarin; Direct factor Xa inh; ( ) Eliquis-Apixaban, ( ) Xarelto- ivaroxaban; Direct thrombin Inh: ( ) Pradaxa- Dabigatran, ( ) Plavix (Clopidogrel)

Goals in management: ( ) DM control, ( ) HTN control, ( ) Stabilization of disease, ( ) Symptom control, ( ) Regression of disease process

Diet: ( ) Low cholesterol diet, ( ) low salt diet, ( ) plant diet, ( ) low fat diet

Referrals: ( ) Vascular surgeon referral, ( ) Cardiology referral, ( ) wound care, ( ) Dietitian, ( ) Nutritionist

Education: ( ) medication compliance, ( ) preventive measures, ( ) follow up care, ( ) Care of wounds



Reviewed by: _____ **Signature:** _____ **Date:** _____

Appendix E:

Project Process Flowchart