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Peripheral Arterial Disease Screening of an Underserved High Risk Population

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PERIPHERAL ARTERIAL DISEASE SCREENING OF AN UNDERSERVED HIGH RISK POPULATION

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ABSTRACT

Disparity in access to health care and preventive services places a heavier burden of morbidity on those with limited access and resources. Underserved populations with decreased access to appropriate health screening and therapeutic interventions often present with increased risks for peripheral arterial disease. Some patients with peripheral arterial disease are asymptomatic and may defer treatment while others present with occlusive disease requiring immediate therapy. Delaying diagnosis and treatment reduces quality of life and functional status. The prevalence of peripheral arterial disease has been extensively studied in the elderly population but the prevalence in the high-risk underserved population is unknown. The purpose of this study was to identify the prevalence of peripheral arterial disease in an underserved, high-risk, predominantly African American population and to determine if providers using an electronic blood pressure machine could accurately measure the ankle-brachial index. The sample population of forty adult residents at a homeless shelter in northeast Florida was screened for peripheral arterial disease. Inclusion criteria consisted of a diagnosis of hypertension, hyperlipidemia, diabetes or a history of smoking. The ankle-brachial index was assessed using the vascular Doppler method and an electronic blood pressure machine though the latter was found to be an insensitive screening tool. The ankle-brachial index, the San Diego Claudication Questionnaire and a physical assessment were used in this cross-sectional study to determine the prevalence of peripheral arterial disease. An abnormal ankle-brachial index value (≤ 0.90), indicating a high suspicion of peripheral arterial disease, was assessed in 22.5% of the sample population, all of whom were found to have a history of smoking crack cocaine.

CHAPTER ONE

INTRODUCTION

Peripheral arterial disease (PAD) is significant, largely undiagnosed and undertreated in primary care practice (Treat-Jacobson & Walsh, 2003). High-risk underserved populations, with limited access to appropriate health screenings or therapeutic interventions often present with multiple complications that contribute to PAD, a manifestation of systemic atherosclerosis. Most patients with PAD are asymptomatic but their risk of cardiovascular events and death is equal to that of patients with symptomatic disease (Khunti, 2003).

The diagnosis and treatment of this disease poses challenges as most health care providers' link atherosclerosis with heart disease and not necessarily PAD. Primary care providers can readily identify the classic presentation of acute myocardial infarction (AMI) and link the problem with coronary artery disease. Most are able to explain the pathophysiology of the disease as an inflammatory process leading to atherosclerotic deposits narrowing coronary arteries. Total myocardial arterial occlusion may ensue causing tissue necrosis leading to significant morbidity and mortality. Prevention and detection of heart disease and its risks are commonplace. Yet, how many could recognize that a patient presenting with classic signs and symptoms of AMI may also have peripheral arterial disease?

Diehm et al. (2004) acknowledge that PAD prevalence data in primary care is limited despite its vital importance to improve treatment outcomes. Experts call for the development of enhanced PAD screening strategies to reduce the risks of cardiovascular and cerebrovascular events in the community.

PAD is a progressive occlusion of the arteries supplying the peripheral vasculature (Bordeaux, Reish, & Hirsch, 2003; Schainfeld, 2001). The carotid, abdominal and lower extremity arteries are commonly affected by this disease. Stühlinger and Tsao (2003) describe PAD as a process whereby the affected vessel lumen narrows or becomes obstructed impeding normal metabolic processes ultimately leading to significant peripheral arterial occlusion. The pathogenesis of PAD is atherosclerosis, the same disease that causes narrowing of coronary arteries leading to acute myocardial infarction.

This study addresses the significant problem of lower extremity PAD and its impact on a high risk, underserved, predominantly homeless African American population residing in a north east Florida homeless shelter. The important role of primary care providers, particularly the role of the primary care nurse practitioner in identifying PAD by screening for the disease using the ankle brachial index (ABI) is delineated.

Background

Sources vary but most report that 8-12 million Americans are affected by PAD (Lesho, Manngold & Gey, 2004; Hirsch, Criqui, Treat-Jacobson, Regensteiner, et.al, 2001). Prevalence data for PAD is equal for men and women and ranges from 12- 20% according to the American Heart Association (n.d.) however Hirsch et al. reported a prevalence of 29% (2001) in a sample population with an average age over 70 years.

Based on data from the National Health and Nutrition Examination Survey 1999-2000, the prevalence among U.S. residents ≥40 years was 4.3% or approximately 5 million people (Selvin & Erlinger, 2004). Age is a major risk factor, as is the presence of diabetes mellitus and smoking. Other important risk factors include poorly controlled hypertension, hyperlipidemia, C-reactive protein and hyperhomocysteinemia (Schainfeld, 2001).

More than 20% of those with PAD experience walking induced intermittent claudication in the lower back, buttock, hip, thigh, calf or foot arch of one or both legs that diminishes with rest (Comerota, 2003). Intermittent claudication is pain that can be described as cramping, burning or aching and may cause numbness (Meru, Mittra, Thyagarajan & Chugh, in press). The severity may increase over time and the disease progressively blocks blood flow in the affected extremity. Collateral circulation may ensue effectively bypassing the narrowed artery limiting symptoms in some individuals 3with PAD. In others, the severity of PAD slowly increases causing limitations and up to 4% of those with the disease may require amputation (Sheehan, et al., 2003). Conducting a history and physical exam helps the provider diagnose symptomatic PAD. History of cigarette smoking, diabetes, hypertension and hyperlipidemia raise suspicion for the disease. Differential diagnoses include spinal stenosis, lumbar disk disease, diabetic neuropathy and arterial embolism.

Obtaining an ankle-to-arm ratio of systolic blood pressure using a standard blood pressure cuff and a hand held Doppler device is a useful screening tool for PAD (Hirsch, Gloviczki, Drooz, Lovell & Creager, 2004; Leng, Fowkes, Lee & Dunbar, et al.1996; Sheehan et al., 2003). Those with abnormal screening ratios for PAD are referred to

specialists for further workup, diagnosis and treatment. Specialists rule out other causes of pain through careful questioning and physical examination. Diagnosis of PAD is often done by an interventional radiologist who performs a catheterization and injects contrast material into the abnormal blood vessels. Radiographs by digital subtraction angiography or a video are obtained. Areas of vascular stenosis are reviewed in conjunction with history and physical findings.

Stenotic vessels should be initially managed with exercise training and risk factor modification but can also be treated pharmacologically (Lesho, Manngold & Gey 2004) or by a variety of techniques including balloon angioplasty, stents, bypass surgery, and grafts (Seiggreen & Kline, 2004). Medical management often includes antiplatelet therapy, medications that decrease vascular viscosity/ promote vessel flexibility and anticoagulants.

Role of Health Care Providers

Physicians, nurse practitioners, registered nurses and other medical and nursing staff are responsible for detecting those at risk for PAD. Primary care providers, such as family physicians and family nurse practitioners play a critical role in the screening and diagnosis of PAD. Experienced nurses, specifically trained in Doppler ultrasound assessment can incorporate this vital procedure into routine evaluation of patients at risk for atherosclerosis and PAD. A high index of suspicion is needed in this setting as nearly 70% of the patients are asymptomatic. Khunti (2003) suggests that screening should be targeted to smokers and persons with hypertension, diabetes, and hypercholesterolemia. The National Heart Lung and Blood Institute workshop also identified elevated fibrinogen, hyperhomocysteinemia and increased C-reactive protein as PAD risk factors (2003). In underserved populations, these known risks for cardiovascular disease and

PAD often go undetected and untreated (Politzer, Schempf, Starfield, & Shi, 2003), progressively damaging the vasculature.

It is important that all involved in detection of PAD know that the ABI may be falsely elevated, especially in long-term diabetics and may signify non-compressible arteries due to calcification (Fahey, 1999; Sheehan et al, 2003). Accuracy of results may be limited in renal failure, obesity, systolic heart failure and vascular calcification. Therefore, the diagnosis of PAD may be missed. Annual ABI measurements may aid prognosis, particularly in patients without classic symptoms due to peripheral neuropathy (Wasserman, 2001). According to Ouriel (2001), Doppler ankle-brachial index screening should be routinely incorporated into the diagnostic workup when evaluating patients at risk for atherosclerosis. Aggressive management of modifiable risk factors and antiplatelet therapy are secondary and tertiary prevention strategies for PAD patients (Hiatt, 2001).

Problem

The National Heart Lung and Blood Institute (NHLBI) (2003) identified PAD as a significant health problem that is under-recognized. There are many barriers to diagnosis of PAD including a lack of familiarity with typical symptoms, restriction of time spent with patients in the primary care setting, inability to perform screening measures and limited referrals to specialists. The ABI is a quantitative assessment of the severity of PAD in nearly all affected individuals, whether or not they are symptomatic (Goodal, 2000). Although obtaining an ABI is non-invasive, inexpensive and well-tolerated (De Sanctis, 2001), many primary care providers do not perform the test themselves nor do

they refer patients for screening resulting in the problem of under-diagnosis and under-treatment.

Screening for PAD in underserved or homeless populations is more difficult to accomplish because these individuals may not seek care. Additionally, providers may not think about PAD screening when a homeless patient presents for another problem. Primary care providers need to be aware of the asymptomatic nature of PAD in the underserved in general and have a high index of suspicion for the disease. Identifying those with known risk factors for cardiovascular disease is paramount in this population (Politzer, Schempf, Starfield, & Shi, 2003).

Purpose & Research Questions

The purpose of this cross-sectional, descriptive study was twofold. The first goal was to determine the prevalence of PAD in a high-risk, underserved, predominantly African American, homeless population. The second goal was to determine if the electronic blood pressure (oscillometric) machine (EBM) could accurately measure ABI compared to findings obtained by Doppler technique.

Two research questions were addressed in this study. The first asked "What is the prevalence of peripheral arterial disease in the target population" and the second asked "What is the efficacy of using an EBM versus a Doppler for ABI screening?" Efficacy in this setting means the ability of the EBM to obtain the same result as the Doppler for ABI.

Variables

The antecedent variables were the participant's gender, pre-existing disease status, ethnicity, physical assessment, claudication questionnaire results and smoking

status. The predictor variables were age, blood pressure, fasting blood glucose, glycosylated hemoglobin level (HgbA1c), total cholesterol, low-density lipoprotcin level (LDL), pack-year history and ABI. The ABI ratio is the criterion variable for which the first research question is based. The following theoretical and operational definitions were used.

Diabetes. Diabetes mellitus (DM) is any of a variety of abnormal conditions characterized by inadequate secretion or inefficient utilization of insulin, over-production of urine, excess glucose found in blood or urine and insatiable thirst. DM is a disorder of carbohydrate metabolism due to heredity or environmental factors (Pease, 2002). In this study, previously documented DM operationally confirmed presence of the disease and level of diabetic control was measured by fasting blood glucose and HgbA1C.

Hypertension. Hypertension is arterial blood pressure that is abnormally high. For the purpose of this study, prehypertension, stage 1 hypertension and stage 2 hypertension based on the Seventh Report of the Joint National Committee (JNC 7) will categorically define hypertension. Patients with a systolic pressure of 120-139 mmHg or a diastolic pressure of 80-89 mmHg are considered pre-hypertensive. Stage 1 hypertension is indicated by a systolic of 140-159 mmHg or a diastolic of 90-99 mmHg and Stage 2 by a systolic $\geq$160 mmHg and a diastolic $\geq$100 mmHg. (U.S. Department of Health and Human Services, 2004). The ADA suggests that diagnosed diabetics control BP to <130/80 (Saydah, Fradkin, & Cowie, 2004). In this study, previously documented hypertension operationally confirmed presence of the disease and blood pressure control was measured by resting blood pressure at the time of data collection.

Hypercholesterolemia. Hypercholesterolemia is a condition in which excess lipids are found in the blood. For the purpose of this study a total cholesterol of >200mg/dL and/or LDL levels >100mg/dL constitute the operational definition of hyperlipidemia. Hyperlipidemia is also known as dyslipidemia and hypercholesterolemia in the literature.

Smoker. A smoker is defined as a person who smokes tobacco or crack cocaine habitually. A documentation of crack cocaine smoking is also noted if provided by the resident. Residents in the sample population are not permitted to smoke while in the program; therefore, as the study commenced, those identified as smokers were not smoking at the time. The operational definition of smoker was any patient who previously identified him or herself as such. A pack year history or years of cigarette or crack use was recorded if provided by the participant.

Ankle-brachial index. An ankle-brachial index is the ratio that is obtained by establishing the systolic blood pressure in each ankle and dividing it by the highest brachial systolic pressure (Leng, Fowkes, Lee, Dunbar, & et al, 1996). For the purpose of this study, a patient was classified as having PAD if they had an ABI≤0.90 (Hirsch et al., 2001; Leng, 1996). Two techniques, the gold standard, hand-held vascular Doppler and an electronic blood pressure machine (EBM), were used to evaluate ABI for this study.

Peripheral arterial disease. PAD is a condition in which progressive occlusion of blood vessels occur, particularly in the extremities. PAD has also been expressed as peripheral arterial occlusive disease (PAOD), lower extremity occlusive disease (LEAD) and peripheral vascular disease (PVD) in the literature (Bordeaux, Reish, & Hirsch, 2003).

Theoretical Framework

Milio's (1976) framework for prevention provided the theoretical background for this study. Milio's strategies encompass concepts of health promotion and disease

prevention central to primary care, advanced nursing practice and underserved populations. Basically, Milio believed that the health status of individuals largely depends on the appropriateness and availability (excess or deprivation) of health-promoting resources. Healthy behavior patterns result from an individual's personal values and available resources, either actual or perceived. Additionally, institutional behaviors by governmental, corporate and policy making organizations dictate "available" options for individuals. Consistent provision and accessibility of health-generating behaviors instead of those that are health-damaging allow for individual assimilation. Education programs and related counseling promote health through personal, social and cultural changes. In other words, those raised to seek health care through the emergency department (ED) are less likely to integrate the philosophies of health promotion and disease prevention. If health care resources were accessible and available, then ED visits would diminish.

Success in healthcare delivery and outcomes for underserved populations require utilization of appropriate, timely, and culturally-sensitive healthcare and education including referral to social services and community based primary care services (Politzer, Schempf, Starfield, & Shi, 2003). Culturally sensitive education is an important measure necessary to facilitate positive personal values for health-generating behaviors (Milio, 1976). Underserved populations, such as the participants in this study, infrequently if ever receive comprehensive management of their healthcare needs. The provision of acute and chronic disease management must be augmented with appropriate screening and education for encouragement of health-generating behaviors

Nurse practitioners often provide community based primary care to a variety of populations such as the elderly, school health and disabled. Those nurse practitioners delivering care to the poor, homeless and underserved must be cognizant that these populations have an increased mortality and morbidity (Politzer et al.) and that living in low income and disadvantaged neighborhoods increases cardiovascular disease risk (Sowers, Ferdinand, Bakris, & Douglas, 2002). Primary care nurse practitioners are educated and trained to offer expansive preventive services to those at risk for vascular diseases and it is imperative that PAD is not overlooked particularly in a high risk, underserved population.

Summary

This chapter provided a brief introduction to PAD and the implications for screening a high risk, underserved population. The significance of PAD risk assessment and utilization of the Doppler ABI screening tool for the primary care provider were examined followed by a description of the study's purpose, variables and theoretical framework. A review of the literature is highlighted in chapter two, which will examine peripheral arterial disease progression in greater detail and analyze recent clinical study results.

CHAPTER TWO

REVIEW OF LITERATURE

Peripheral arterial disease is a vascular disorder affecting eight to twelve million Americans and causes significant morbidity and mortality (American Heart Association, n.d.). Those with the disease have a fivefold increased risk of death from heart attack or stroke. Vascular Disease Foundation president Alan Hirsch, MD has pioneered a national PAD awareness campaign due to its association with significant detrimental effect on functional status, quality of life and amputation risk (Hirsch et al. 2004). The disease is of significant importance to primary care practitioners because PAD is markedly under-diagnosed and under-treated (Norman, Eikelboom & Hankey, 2004). High risk, underserved populations, with limited access to appropriate health screenings or therapeutic interventions often present with multiple complications that contribute to PAD, a manifestation of systemic atherosclerosis.

Most patients with PAD are asymptomatic but their risk of cardiovascular events and death is equal to that of patients with symptomatic disease (Khunti, 2003). Diehm et al. (2004) acknowledge that PAD prevalence data in primary care is limited despite its vital importance to improved treatment outcomes. These researchers call for the development of enhanced secondary prevention strategies of cardiovascular and cerebrovascular events in the community. Effective screening for PAD in all primary care settings may increase the chance of early diagnosis and treatment. Currently, asymptomatic screening for PAD is not recommended (USPSTF, 2005).

This review of the literature will examine the pathophysiology, signs and symptoms, risk factors and disease progression. In addition, screening and diagnostic methods, diversity issues and recent research findings are provided which represent the state of science in PAD.

Pathophysiology of PAD

Atherosclerosis is the most common cause of PAD (Lewis, 2001, Sieggreen & Kline, 2004). Atherosclerosis, which begins as an insidious process, actually accounts for approximately 90% of arterial extremity pathology (Cimminiello, 2002). Endothelial cells lining the arterial walls may become injured through many factors including: smoking; diabetes; hypertension and dyslipidemia. The degenerative inflammatory process known as atherosclerosis begins as endothelial injury with progression of a fatty streak and then a fibrotic plaque which adheres to the lining and obstructs peripheral blood flow. Oxidized low density lipoproteins (LDL) engulfed by macrophages form foam cells known to be destructive to the lining of the intima. Fatty streaks are the accumulation of numerous foam cells. Fibromuscular lesions develop when collagen and smooth muscle proliferation migrate over the fatty streak leaving a fibrotic plaque that destroys underlying tissue. The process further decreases arterial lumen diameter and impedes oxygenation and organ perfusion. The sequelae of this course may lead to tissue necrosis and rupture of the vessel (Lewis, 2001; McCance & Huether, 2002).

Narrowing and hardening of the vessel caused by atherosclerosis leads to an inadequate blood supply in the peripheral arteries. Exercise creates increased demand for oxygen. Insufficient perfusion to the vasculature creates an anaerobic state which causes the muscles to produce lactic acid (Meru et al., 2005). The resultant cramping and pain is known as intermittent claudication, which usually occurs with an ABI between 0.30-0.90 (DeSanetis, 2001).

Signs and Symptoms

It is estimated that approximately 75% of PAD patients are asymptomatic. Since PAD is often found with advanced age or in combination with other diseases, the patient and provider may attribute progressive lower extremity discomfort, reduced sensation and limited ambulation to the aging process. Asymptomatic PAD has been associated with reduced quality of life and impaired lower extremity functioning including; slower walking velocity, poor balance, shorter walking distances and impaired ability to repeatedly rise from a sitting position (McDermott, Fried, Simonsick, Ling, & Guralnik, 2000). Without diagnosis or therapeutic intervention, development of a more advanced, painful stage may ensue.

Intermittent claudication. The most common presentation of symptomatic PAD is intermittent claudication (IC), typically manifested by aching pain, weakness, numbness or fatigue in lower extremity muscle groups (Bick, 2003; Schainfeld, 2001).

Acute claudication. Symptoms of IC initially occur during exertion and disappear during rest (Cassady, 2004; Cimminiello, 2002). At this stage, the patient may walk a shorter distance at a slower pace and experience discomfort. Diminished or absent pulses, low skin temperature, hair loss and poor capillary refill may also be present (Goodal, 2000). As the severity increases, symptoms of claudication may become debilitating reducing functional ability, quality of life and altering body image. This may cause a significant emotional and fiscal burden to the patient, family and community.

Critical limb ischemia. Critical limb ischemia (CLI) exists when the patient experiences pain at rest, exacerbated by the supine position. Relief may only be possible by placing the legs in a dependent position, such as dangling over the side of the bed. At this stage, non-healing wounds, lesions, ulcers and gangrene, which are limb-threatening complications of PAD, (Sheehan et al. 2003) may result, requiring revascularization surgery or amputation (Burns, Gough, & Bradbury, 2003).

Insufficient perfusion to the extremities develops due to acute obstruction or is the result of progressive chronic occlusion of the peripheral vasculature. Clinical manifestations of PAD may not be realized for decades, although the detrimental effect continues. Aging, toxins and comorbidities adversely affect the smooth intimal lining found in otherwise healthy arteries increasing the risk of developing PAD.

Risk Factors

Diabetes. PAD is a major factor in lower extremity amputation, especially among diabetics (Sheehan et. al., 2003). Diabetics and smokers are at risk for developing peripheral neuropathy with resultant impaired sensory perception (Sheehan et al). Damaged sensorineural receptors impair responses to pain and injury. Peripheral neuropathy often complicates the discovery of PAD (Mitka, 2004). Undiagnosed and uncontrolled diabetics are at an increased risk of developing the complications of physical walking limitations and a reduced quality of life (Oka & Sanders, 2005). Further, HgbA1C levels ≥5.3% are associated with higher risk of PAD (Muntner, et. al., 2005). Diabetics have a 2-4 fold increased risk of developing PAD (NHLBI, 2003). The American Diabetes Association (ADA) Consensus Panel suggests that patients ≥50 years of age with diabetes and ≥40 years of age with diabetes and additional cardiovascular disease risks should be screened using the ABI (Sheehan et al.) annually since atherosclerosis is known to occur earlier in diabetic patients, causing reduced functioning of the lower extremities (Dolan et al., 2002; Gordon, 2004).

Hypercholesterolemia. Hypercholesterolemia is present in approximately 40% of patients with PAD (Stühlinger & Tsao, 2003). An increased level of LDL is associated with the progression of atherosclerosis which coincides with the development of endothelial dysfunction. Arterial occlusion is the negative sequelae of chronic, untreated atherosclerosis.

Hypertension. Fifty million Americans are affected with the nation's most common primary diagnosis, hypertension, which also affects 50-92% of patients with PAD (Olin,

2005). Arterioles undergo hypertrophy and hyperplasia in chronic hypertension due to prolonged vasoconstriction and increased vascular pressure. The resultant decrease in lumen diameter and stiffening of the vessels leads to an increased risk for PAD.

Smoking. Valentine et al. (2004) concluded that both smokers and individuals with a family history of CVD were more likely to develop arterial lesions. In addition to the damage caused to the endothelial lining, smoking increases coagulation, exacerbating the progression of atherosclerosis (Bordeaux, 2003) caused by the reduction of nitric oxide dependent vasodilatation (Cimminiello, 2002). The incremental risk for developing PAD in smokers is three to fivefold (NHLBI, 2003). A systematic review of the incidence and prevalence of PAD by Willigendael et al. (2004) observed that smoking is reported by 50% of patients with disease. Their analysis also concluded that former smokers have a 2.6 fold increase in risk of asymptomatic PAD.

Disease Progression

Patients with PAD have a considerable increase in comorbidity burden (Kugler and Rudofsky, 2003). Patients with intermittent claudication have a 10-year mortality rate of 60% and report that the symptoms adversely affect their quality of life, functional status, home-management skills, social interactions and ambulation. Though rare, approximately 4-5% of PAD patients may have a resultant amputation (Sheehan et al. 2003). Hirsch (2003) claims that under-diagnosis of PAD in primary care hinders secondary cardiovascular disease (CVD) prevention practices, including aggressive treatment for diabetes, hyperlipidemia, hypertension and smoking cessation. Relevant history taking and awareness of subtle signs are frequently overlooked in the absence of classic symptoms of claudication (Lesho et al., 2004). Early diagnosis of PAD is of critical importance because it is a powerful predictor of future cardiovascular events such as myocardial infarction, cerebrovascular accidents and death (Diehm et al., 2004).

Screening and Diagnosis

Unless specifically questioned by the primary care provider to ascertain vascular health status, the signs and symptoms may remain undetected and the disease will be undiagnosed and untreated (Goodal, 2000). Most of the risk factors for PAD are controllable through lifestyle modification and therapeutic intervention. The most significant modifiable risk factor is smoking (Lesho et al., 2004). Hypertension, diabetes, hyperlipidemia, obesity and inactivity are additional examples of manageable risks. Non-modifiable risk factors are advanced age, family history, male gender (Bordeaux et al., 2003) and ethnicity (Collins, Petersen, & Suarez-Almazor, 2003).

At all stages along the screening and diagnostic process for PAD, the practitioner must be cognizant of available physical and verbal assessment tools. In addition to performing the ABI, patient education and behavior modification are essential for patient commitment to a therapeutic regimen designed to reduce other cardiovascular and cerebrovascular events, limb loss and death. Risk factor management is the key to delaying the progression of PAD. Aggressive treatment of hypertension, hyperlipidemia, diabetes and a smoking cessation program have been routinely advocated (Treat-Jacobson & Walsh, 2003). Routine screening in asymptomatic adults has not been recommended by the U.S. Preventive Services Task Force (USPSTF, 2005). Saydah et al. (2004) support the standards of medical care set by the ADA for the reduction of CVD complications in diabetics. The ADA advocates that goals for diagnosed diabetics to be an HgbA1c <6%, BP<130/80, and LDL <100mg/dL.

Current Research Findings

Many recent PAD studies can be found in the literature. Reports by the Vascular Disease Foundation explain the necessity for mandating the creation of a national public awareness campaign for PAD (Hirsch et al. 2004). As is reflective of most PAD investigations, the sample populations used in these studies are predominantly elderly Caucasians.

In PARTNERS, an interdisciplinary, cross-sectional PAD detection program, investigators analyzed 6879 patients over ages 50 and older with a history of smoking or diabetes; in 350 U.S. primary care practices. Although there was a PAD prevalence of 29% of patients diagnosed by an ABI of <0.90 with PAD, only 8.7% had IC symptoms. Primary care utilization of IC symptoms alone for PAD diagnosis will miss more than 85% of PAD (Hirsch et al., 2001). Broader screening may reduce the barrier to effective secondary cardiovascular disease prevention methods. Physician awareness of prior diagnosis of PAD was only 49%. PAD patients received less aggressive treatment than was provided CVD patients. These researchers advised that screening with a simple ABI measurement will identify many previously undiagnosed PAD patients and suggested that enhanced diagnostic efforts and appropriate therapeutic interventions in primary care practices are required to restrict critical limb ischemia, amputation and cardiovascular risk to improve quality of life.

Researchers from the Women's Health and Aging Study (WHAS) analyzed the prevalence of asymptomatic PAD among 1002 community dwelling, disabled women between 65-85 years of age (McDermott et al., 2000). The authors reported the prevalence of ABI<0.90 to be 35% of the target population. Also noted was that the majority of patients with PAD did not experience exertional leg pain, but lower ABI levels were related to progressively poorer functioning of the lower extremities (McDermott et al.). The General Internal Medicine (GIM) study, conducted by the same primary investigator focused on 382 men and women over 55 years of age. They found undetected PAD in 14% of the patients and in previously diagnosed patients, only 44% had exertional leg symptoms. Cigarette smoking was significant in undiagnosed PAD patients (McDermott et. al., 2001). Finally, these investigators attributed functional lower extremity impairment to undiagnosed PAD patients and concluded that without ABI screening, PAD is difficult to diagnose.

The German Epidemiological Trial on Ankle Brachial Index (getABI study), was a large-scale, cross sectional study in which investigators assessed 6,880 men and women (mean age 72.5 years) in German general medicine practices (Diehm et al., 2004). An analysis of ABI, physical exam, comorbidities and the WHO questionnaire on intermittent claudication were performed to determine the prevalence and cormorbidity of PAD. Researchers concluded that history and physical examination of a patient are insensitive for diagnosing PAD and recommended ABI screening. Eighteen percent of their sample population had an ABI<0.90, with a higher prevalence in men (19.8%) than women (16.8%). The prevalence of PAD patients with CVD, diabetes, hypertension, hyperlipidemia and a history of smoking were also higher than in those without PAD. As has been found in other studies, the WHO/Rose questionnaire on intermittent claudication only confirmed 11% of the PAD patients (Leng & Fowkes, 1992).

Researchers in another study compared comorbidity and quality of life indices of 101 symptomatic men and women (mean age 66.4) with those of 89 asymptomatic community-dwelling elderly individuals (mean age 77.4) and 439 geriatric nursing home residents (mean age of 84.1). Comorbidity indices and illness severity using the cumulative illness rating scales (CIRS) were significantly higher in the symptomatic PAD patient group. Additionally, quality of life subjective health status scores worsened with advanced stages of PAD and IC. In fact, researchers indicated the 10-year mortality rate associated with IC might be as high as 60% (Kugler & Rudofsky, 2003).

The Atherosclerosis Risk in Communities Study (ARIC) was a prospective cohort study identifying PAD risk factors in 15,972 patients with diabetes, ages 45-64 years. Participants were white and black men and women represented from four communities throughout the United States. Analysis of study participants was conducted over a 10.3 mean year period at three year intervals. Of the participants with diabetes, 238 developed PAD. A low ABI was the only means by which PAD was detected in 110 of the participants. The study concluded that the risk of developing PAD in diabetics was

increased 1.87-fold (95% CI, range 1.36-2.57). In current smokers, the risk increased to 2.27 (95% CI, range 1.57-3.26) and in participants with baseline CHD, a 1.75-fold increased risk (95% CI, 1.18-2.60) was demonstrated (Wattanakit, K. et al., 2005).

The prevalence of lower-extremity disease in U.S. adults' ≥40 years of age regardless of diabetic status was reported by Gregg et al. (2004) based on the 1999-2000 National Health and Nutrition Examination Survey. This study concluded that 4.5% of participants had lower-extremity disease. PAD was twice as common in diagnosed diabetics-9.5%, and affected the elderly, non-Hispanic blacks and Mexican Americans in greater proportion. Each gender was represented equally in this sample of 2,873 men and women with a mean age were 56.9 years. The population was 75% white, 9.6% black and 4.5% Hispanic. Diabetes had been diagnosed in 9.9%, hypertension in 36%; CVD in 11.5% and 53% had a history of smoking. The study concluded that their prevalence rate of PAD, which is lower than reported by most studies, was due to the younger age of their sample population. A call for increased assessment, prevention and CVD management efforts were recommended (Gregg, et. al., 2004).

A study of racial diversity as it relates to the prevalence of PAD was reviewed. Four hundred and three Caucasians, African Americans and Hispanics > 55 years of age, residing in lower income households near four Houston primary care clinics were screened (Collins et al., 2003). Physical assessment including an ABI, difficulty with walking, medical history and quality of life were performed in addition to evaluation of questionnaires concerning symptoms of IC. The prevalence of PAD in African Americans (22.8%) was higher than in Caucasians and Hispanics (13.5%) with a combined total of 18% PAD in the general medical practice. Smoking (29.9%), diabetes (55.2%) and hypertension (82.1%) were all more prevalent in patients diagnosed with versus patients without PAD. Prior PAD diagnosis was more likely in Caucasians than African Americans or Hispanics. Asymptomatic PAD was found in 37% of the diagnosed patients. Researchers found the San Diego Claudication Questionnaire (SDCQ) and the

Walking Impairment Questionnaire (WIQ) individually to have low sensitivity for PAD when compared to ABI, the gold standard for diagnosis due to the late onset of symptoms. Quality of life scores for physical function and role limitations were significantly lower in PAD patients. Concern for quality of life in chronic illness prompted the authors to promote the ABI screening tool for CVD at risk patients. Collins et al. observed that African Americans have approximately two times the prevalence of PAD than Caucasians and Hispanics. Though little PAD research has been conducted with diverse populations, further studies have been suggested to clarify the actual prevalence, especially in the medically underserved.

Researchers in the Atherosclerosis Risk in Communities Study reported that the incidence of PAD in African American women with Type 2 diabetes is 2.4 times that of Caucasian women aged 45-64 years (Sowers et al., 2002). The prevalence of hypertension and CVD is also reported to be substantially higher in African Americans. Environment, diet and access to health care contribute to an earlier onset of CVD with increased mortality rates (Sowers et al.). Additionally, the uninsured, underserved population is less likely to seek health care until disease progression has deteriorated significantly (Hafner-Eaton, 1993). Therefore, those who are poor should anticipate more chronic illnesses and a decreased lifespan (Politzer et al, 2003).

Though no major clinical research studies have been conducted on the association of cocaine or crack and PAD, two patients with cocaine-induced peripheral vascular occlusive disease were reported in a case study by Gutierrez, England and Krupski, (1998). One 37 year old man presented within hours of smoking crack cocaine complaining of severe pain and numbness in both feet. Although intervention was extensive, he eventually required bilateral below the knee amputations. The second patient was a 22 year old female with bilateral pedal burning pain and numbness who presented within an hour of smoking crack cocaine. As with the previous patient, both of her feet were cold with diminished peripheral pulses. After treatment, the second patient

suffered no long-term negative sequelae. Cocaine's effect causes intense vasoconstriction, increased atherogenicity and dysfunctional production of relaxin factor production in the endothelium according to these authors. Gutierrez et al. acknowledge that cocaine-induced coronary artery vasoconstriction is well documented, but its influence on the peripheral vasculature warrants further investigation.

Summary

Each of the PAD studies reviewed indicates a high prevalence of an undiagnosed, asymptomatic condition often overlooked in primary care practice. The research has focused mainly on elderly Caucasians. Though the prevalence of PAD increases with age, underserved populations suffer a disproportionate burden of chronic illness including hypertension, diabetes and CVD. PAD, which is a systemic manifestation of atherosclerosis, presents often with other CVD comorbidities, particularly in smokers. Broader screening measures, including the gold standard ABI, have been advocated by many experts interested in early detection of PAD in order to promote vascular health and maintain quality of life (Heidrich, Wenk, & Hesse, 2004). This coincides with Milio's framework for prevention, which challenges the health care delivery system to provide state of the art modalities and promote health-generating behaviors in underserved populations.

CHAPTER THREE

METHODOLOGY

The purpose of this cross sectional descriptive study was to determine the prevalence of PAD in a high-risk, underserved predominantly African American homeless population and to determine if an electronic blood pressure machine could accurately measure ABI. The assessment will be done through physical examination, the San Diego Claudication Questionnaire (SDCQ) and ABI analysis. The sample population was largely African Americans who are at greater risk for developing cardiovascular diseases. A comparison of hand-held Doppler blood pressure readings versus the use of an electronic blood pressure machine for ABI assessment was conducted. The review of literature indicated that the prevalence of PAD is as much as 29% (Hirsch et al., 2001) in the primary care setting. Hypertension, hyperlipidemia, diabetes and cigarette smoking compound the risk for PAD, cardiovascular disease and cerebrovascular events. As has been documented, PAD is underdiagnosed and undertreated in the primary care setting. Given that the majority of patients are asymptomatic or have atypical presentations, secondary prevention strategies are limited. Evaluation of diabetics for PAD may be more difficult due to decreased sensory perception from peripheral neuropathy and distal vessel lesions, though the incidence of PAD in diabetics is more prevalent than in nondiabetics. Reduction of dyslipidemia and hypertension are advised to reduce the risk of claudication and to promote cardiovascular health. The most important modifiable cardiovascular risk factor is smoking. Tobacco use is highly associated with the development and exacerbation of PAD. Smoking is also linked to the progression of atherosclerosis and an increased amputation risk (Sheehan et al., 2003). This chapter will discuss the methodology used in this study.

Sample

A nonprobability convenience sample of patients at a local shelter was used. Confirmed diagnoses of diabetes, hypertension, hyperlipidemia or history of cigarette or crack cocaine smoking, regardless of age, were the inclusion criteria. A confirmed diagnosis was assumed if documentation in the participant's chart was established and/or the patient was receiving medication for diabetes, hypertension or hyperlipidemia.

Additionally, laboratory or diagnostic values were considered evidence of disease for inclusion criteria in the following instances. Hypertension was assumed if the patient had two or more systolic blood pressures of >129 or a diastolic blood pressure of >80 (Ebell, 2004). History of smoking was established by patient confirmation of prior usage and a years used or pack year value was determined. Hyperlipidemia was assumed if LDL values were >100 and/or total cholesterol was >200. Fasting blood glucose (fbg) over 126 was diagnostic of diabetes.

The target population was predominantly African American, previously homeless, indigent, many with substance abuse histories and limited access to sufficient, appropriate health care, health promotion or disease prevention programs. This group is reflective of the high-risk underserved population in northeast Florida. Available patients, who met the study criteria and gave their consent for participation, represented the sample population

Setting

The setting was the medical clinic at a local shelter which is a faith-based, recovery residence for the homeless and needy in Northeast Florida. In addition to medical care, residents were provided with counseling, education or vocational training and Bible study. The clinic had three patient examination rooms, a nurse's assessment station, a pharmacy and a front office. The facility was adequately equipped to accommodate the proposed study.

Data Collection

The primary investigator conducted all steps of the procedure unless otherwise noted. Review of current patient charts and new patient initial assessments identified the potential sample. Based on inclusion criteria, patients were asked to participate in the study through direct contact by the researcher. The study purpose and procedures were explained and a written consent to participate was obtained (see Appendices A and B).

Once consent was obtained, participants were given an appointment for testing. A physical assessment, patient history and San Diego Claudication Questionnaire results were collected and documented. An ABI assessment was obtained on every participant. The systolic blood pressures from bilateral brachial arteries and from either the dorsalis pedis or posterior tibialis of both ankles were recorded. The ABI Doppler assessment and electronic blood pressure measurements were assessed by the primary investigator, a skilled practitioner, using the standard procedure (See Table 3.1). Interpretation of ABI ratio readings is presented Table 3.2. Each participant with an ABI$\leq$0.9 was referred to the medical clinic director and/or a vascular specialist for further evaluation.

Table 3.1 *ABI Measurement Procedure*

Step 1	Rest patient in supine position for five minutes
Step 2	Bilateral brachial systolic BP taken at antecubital fossa using stethoscope and BP cuff, the higher reading will be used to calculate ABI
Step 3	Place appropriate size cuff around right ankle Obtain BP using Doppler at dorsalis pedis or posterior tibialis arteries Repeat step with left ankle
Step 4	ABI is calculated by dividing the higher ankle systolic BP for each leg By the highest brachial systolic BP, record results
Step 5	Repeat procedure using the EBM, record results

(Sheehan et al. 2003; Weber & Kelley, 2003)

Table 3.2 *ABI Interpretation Results*

ABI	0.91 to 1.30	Normal
ABI	≤0.90	Abnormal
ABI	>0.80 to ≤0.90	Mild disease, possibly asymptomatic
ABI	0.50 to 0.80	Moderate disease
ABI	<0.50	Indicative of severe occlusive disease
ABI	<0.25	Typically indicative of ischemic rest pain or tissue loss
ABI	>1.30	Poorly compressible arteries from calcification in diabetes

(Sheehan et al., 2003)

Instruments

Two written instruments were used for this study, a data collection form was developed by the primary investigator (see Appendix A) and the San Diego Claudication Questionnaire (SDCQ) (see Appendix B). The data collection form reflected pertinent diagnoses, physical assessments and clinical impressions. The SDCQ, developed by Michael Criqui, MD, is based on the WHO/Rose intermittent claudication questionnaire and has documented reliability and validity (Criqui et al., 1996). The difference between the SDCQ and the WHO/Rose questionnaire is that the SDCQ is able to provide an evaluation for bilateral results. The questionnaire was administered verbally or given as a self-test, to assess if each patient had no pain, was asymptomatic, had symptomatic PAD or intermittent claudication, which is also identified in the literature as Rose or typical claudication. The SDCQ is an enhanced version of the widely used WHO/Rose intermittent claudication questionnaire developed in 1962 by Leng and Fowkes (1992). Studies have shown the WHO/Rose questionnaire to have a sensitive of 60-68% and a specificity of 90-100% (Cimiminiello, 2002). The SDCQ incorporates revisions made on the WHO/Rose questionnaire to include the evaluation of buttock, thigh and right or left leg specific symptoms. Permission for the SDCQ use was provided by Dr. Criqui (see Appendix C).

Ankle-brachial index, the ratio of the ankle systolic pressure to the brachial systolic pressure was ascertained. This objective test measures the lower extremity arterial

perfusion (De Sanctis, 2001). It has 91.3% sensitivity and 99.3% specificity (Leng & Fowkes, 1992). Instruments used to obtain the brachial and ankle blood pressures were a hand-held 5-10 MHz Doppler and an EBM. The Welch-Allyn Propaq 102 EL vital signs monitor was the EBM used in this study. The hand-held ultrasound Doppler used for this study was the Nicolet Vascular Elite model #100 with an 8MHz probe. Both instruments have been inspected for accuracy and reliability to conform to American Standards for Testing Materials (ASTM) guidelines.

Statistical Analysis

A descriptive statistical analysis was conducted to evaluate the data utilizing SPSS v 14.0 software. The level of data collected and the anticipated findings are provided (See Table 3.3) including research questions and the demographic data.

Protection of Human Subjects

The Institutional Review Board (IRB) of the University of North Florida approved the design and intent of this study for the protection of human subjects. Each subject, prior to participation in the study, completed an informed consent document (see Appendix D). The right to refusal from participation in the study without penalty was offered to each study participant as was the option to discontinue participation at any point.

CHAPTER FOUR

RESULTS

The purpose of this study was to describe the prevalence of PAD in an underserved, high-risk, predominantly African American, homeless population and to determine if the electronic blood pressure machine (EBM) could accurately measure ABI compared to findings obtained by Doppler technique. Over a period of fifteen months, medical clinic patients were evaluated and 56 were enrolled in the study based on eligibility criteria. Due to the transient nature of the shelter, 16 enrollees were unavailable at the time the clinical data were gathered. The total sample size, therefore, was 40.

Demographic Data

The study was conducted at the medical clinic of a residential shelter for the homeless. The average age of the sample was 46.03 years (range =20-59 SD = 9.09). The sample population was 70% male (n=28). Twenty-seven (67.5%) were Black, 12 (30%) were White, and 1 (2.5%) was Hispanic. The mean BMI of the 38 patients for whom these data were available was 29.78 (range = 20.64 to 64.7, SD 8.22).

Figure 4.1 Descriptive statistics

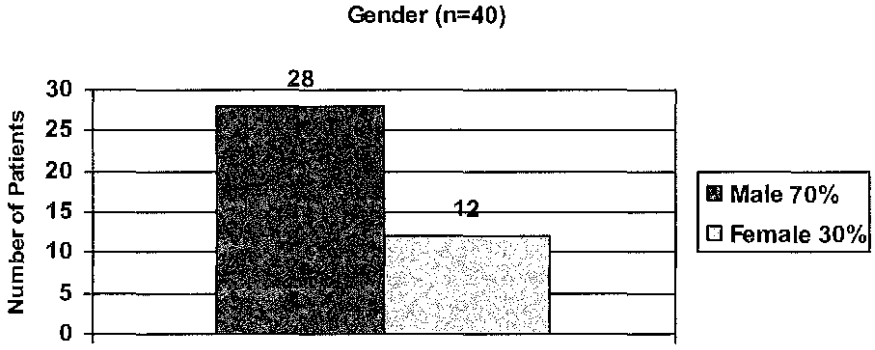
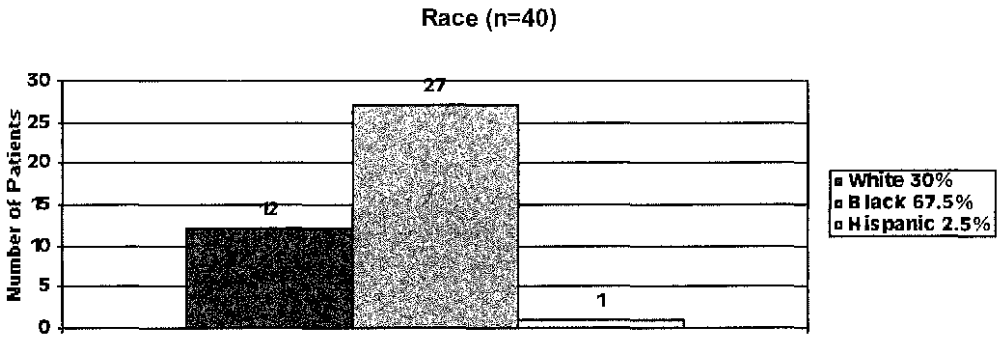


Figure 4.2 Descriptive statistics



Risk Factors

Hypertension, diabetes, hypercholesterolemia and a history of smoking are the comorbidities of cardiovascular disease which were identified and utilized as the eligibility criteria (See Table 4.3).

Hypertension. Of the study participants 55% (n=22) had a diagnosis of hypertension. Twenty of these (90.91%) were on antihypertensive medications. Ten of those patients were on two antihypertensive medications and two patients were on three antihypertensive medications. Of the 22 patients on reported antihypertensive medications, only six had a systolic blood pressure under 120mmHg and a diastolic blood pressure below 90mmHg.

Hypercholesterolemia. Forty-two percent (n=17) of the sample population had a diagnosis of hypercholesterolemia. Eleven of these (64.71%) were on antilipidemic medications. The serum cholesterol readings revealed that four patients had a total cholesterol level under 200mg/dl and five patients had a low density lipoprotein level below 100.

Diabetes. Twelve patients (30%) had a diagnosis of diabetes. All twelve patients were on either oral glucose lowering medications or insulin. Only two patients however, had an HgbA1C under 6.0% or fasting blood glucose under 100mg/dl.

Smoking. Eighty percent (n=32) had a history of cigarette smoking prior to their residence at the shelter. A prior habit of smoking crack cocaine was reported by 85% (n=34).

Table 4.3 *Risk Factor Analysis*

Risk factor	Number	Percent	Minimum	Maximum	Mean	Std Dev	N
Age	40	100	20	59	46.03	9.09	40
BMI	40	100	20.64	64.70	29.78	8.22	38
Hypertension	22	55					
Systolic BP			102	194	140.45	22.85	22
Diastolic BP			64	110	87.45	11.35	22
Hyperlipidemia	17	42					
Total			153	298	215.19	42.08	16
LDL			58	189	124.70	40.91	15
Diabetes	12	30					
Fasting glucose			89	401	198.67	92.83	12
HgbA1C			5.4	18.10	8.27	2.68	12
Smoking							
Cigarette-pk yrs	32	80	1	80	26.69	18.67	29
Crack yrs of use	34	85	0.1	25	9.25	7.63	22

Clinical Assessment

Lower extremities were examined in all study participants with an evaluation of dorsalis pedis and posterior tibialis pulses, pedal temperature, hair loss, capillary refill, thickened toenails, shiny or scaly skin, lesion, ulcer or gangrene, sensory perception and edema was assessed. Bilateral adverse assessment findings were recorded (see Figure 4.3 and Figure 4.4).

Figure 4.3 *Bilateral Extremity Assessment I*

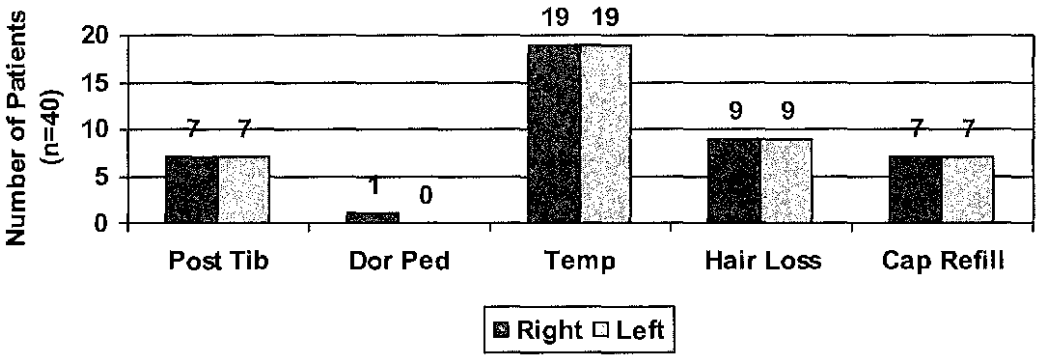
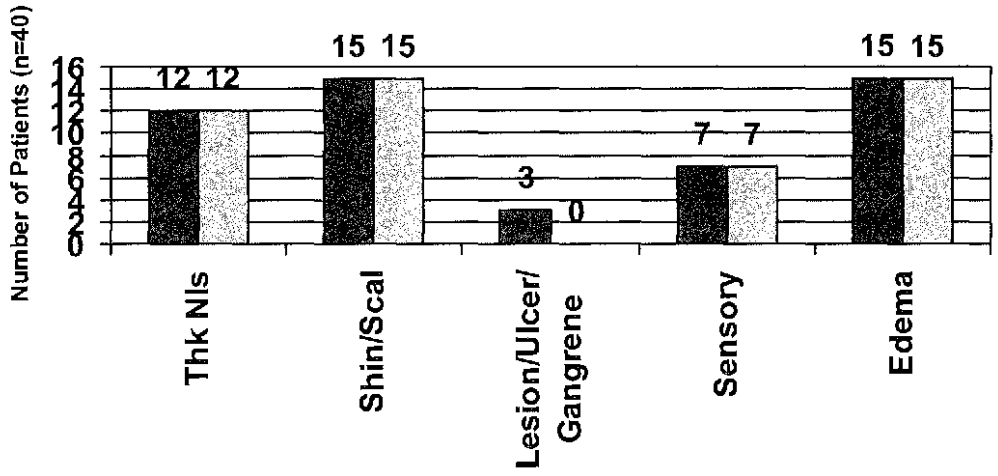
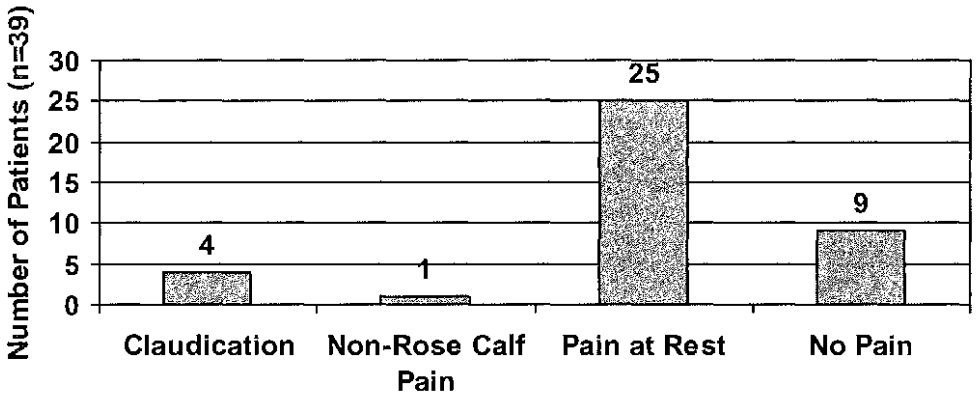


Figure 4.4 *Bilateral Extremity Assessment II*



San Diego Claudication Questionnaire. Thirty-nine of the forty participants completed the questionnaire. Evaluation of questionnaire results using criteria provided by the author revealed that four participants had symptoms consistent with claudication, one participant had non-Rose calf pain, 25 participants had pain at rest, 9 participants reported no pain and one participant did not complete the questionnaire (n=39) (See Figure 4.5).

Figure 4.5 *San Diego Claudication Questionnaire Results*



Ankle-brachial index. The ankle-brachial index was obtained on both the right and left extremity of each study participant using the Doppler method and the electronic blood pressure machine. Using the standard Doppler method, a reading of ≤.90 was obtained in the right extremity of five study participants (12.5%) and in the left extremity in six participants (15%), for a total of 22.5% of the sample population. Two participants had bilateral disease. The electronic blood pressure machine indicated no study participants with an ABI of .90 or lower. Using the Doppler, two right (5%) and two left (5%) extremities revealed an ABI>1.30 while the electronic blood pressure machine revealed an ABI>1.30 in four right (10%) and seven left (17.5%) extremities. This is indicative of non-compressible vessels associated with diabetes.

Table 4.4 presents the demographic data, number of risk factors, results from the San Diego Claudication Questionnaire (SDCQ) and bilateral ABI results using both the gold standard hand-held Doppler and the electronic blood pressure machine for each study participant with an ABI ≤.90.

Table 4.4 *Abnormal ABI Results* (ABI≤0.90*)

Pt	Dem	#RF	SDCQ	ABI by Doppler		ABI Electronic BP	
1	48bm	3C	Rest	R 0.900*	L 1.070	R 1.090	L 1.180
3	37wm	1C	Claudication	R 1.118	L 0.847*	R 1.190	L 1.340
4	45bm	3C	None	R 0.927	L 0.900*	R 1.238	L 1.247
8	56bm	2C	None	R 0.980	L 0.740*	R 0.990	L 0.915
30	45bm	4C	Rest	R 1.060	L 0 .830*	R 1.230	L 1.210
31	50bm	4C	Claudication	R 0.720*	L 0 .909	R 1.090	L 1.009
33	56bm	3C	None	R 0.900*	L 1.010	R 1.240	L 1.130
35	54bm	2C	None	R 0.680*	L 0.780*	R 1.050	L 0.920
40	30wm	1C	Claudication	R 0.690*	L 0.845*	R 1.040	L 0.970

Discussion

All of the study participants with an abnormal ABI were male. Seven of the nine men (78%) with abnormal ABIs were black and 22% (n=2) were white. The mean age of these participants was 46.78 with a minimum age of 30 years and a maximum of 56 years. Eighty-five percent of the entire sample population had a history of crack cocaine use, but in those with an abnormal ABI, 100% had a history of using crack cocaine. Three participants, or 33% reported results consistent with claudication on the SDCQ and only two participants, or 22% had bilateral abnormal ABIs. Using the EBM, no reports of an abnormal ABI were obtained.

CHAPTER FIVE

CONCLUSION

The objective of this study was to identify the prevalence of PAD in residents at a local homeless shelter and to determine the efficacy of using an electronic blood pressure machine to accurately assess ABI. All study participants were identified to have at least one of the risk criteria of hypertension, hypercholesterolemia, diabetes or a history of smoking. It is difficult to determine if this sample is generalizable to national high risk, underserved homeless populations due to an inability to accurately gather census data, however, the study population is reflective of the homeless population at this resident shelter in Northeast Florida.

The importance of this study is the unique view provided professionals of an infrequently studied population since health status analysis of the homeless is complex and rarely reported. National disease prevalence of PAD has been established predominantly through studies with participants who are older, Caucasian and insured. A 29% prevalence of PAD was reported by the PARTNERS study, but it is essential to restate that the average age of that sample was 70 years (Hirsch et al., 2001). The National Health and Nutrition Examination Survey reported a lower-extremity prevalence of 4.5% and a 9.5% respectively in diabetics and non-diabetics (Gregg, et. al., 2004). The prevalence of lower-extremity PAD, indicated by an ABI$\leq$0.90 in this sample, with a mean age of 46.03 years was 22.5% at this local resident shelter in Northeast Florida.

This significance of this finding is reflective of the sample population which is 70% male, 70% non-white and 100% homeless. None of the participants had medical coverage or consistent healthcare. The cardiovascular and cerebrovascular risks suffered by the participants in the study were hypertension-55%, hypercholesterolemia-42% and 30% diabetes. A striking 80% had a history of smoking cigarettes and 85% had a history of smoking crack cocaine.

The use of the electronic blood pressure machine indicated that no study participants had an ABI≤0.90. Furthermore, it is important to reiterate that all study participants were evaluated using both the Doppler and electronic blood pressure machine. The electronic blood pressure machine was found in this study to be an insensitive tool in identifying PAD using the ABI method.

Limitations

The small sample population and the extended period of time that the data was gathered combined with the transient nature of the shelter population limited the ability to achieve exact point prevalence. A probability sample was not possible for this study since the identity and location of all high-risk underserved individuals in northeast Florida is unknown, which is a limitation of the study. Some data were not available when the results were tallied and 16 people whom had given their consent were no longer available for further investigation at the time the study was conducted. Four individuals, who met the criteria, declined participation. The study excluded individuals without the known CVD risk factors of hypertension, hypercholesterolemia, diabetes or a history of smoking potentially resulting in altering the identified prevalence of PAD. The participants were required to refrain from smoking once they entered the residence which may improve

their ABI. Also, no documentation of duration since diagnosis of risk factors or length of treatment was evaluated and no documentation on various test results (e.g. blood pressure, Hgba1C, LDL) was gathered unless the participant had a diagnosis of the specific comorbidity. Most study participants completed their own SDCQ allowing for the introduction of error due to interpretation. An interviewer administered questionnaire was offered to every participant.

Implications for Further Study

The results of this study clearly indicate the importance of further research in the investigation of PAD on a larger scale in an underserved, high risk population. Special attention should be given to the high risk population who are currently smoking and using illicit drugs on a regular basis. The prevalence of PAD in those without known risk factors is of interest since many who are homeless and underserved are unaware that they have certain diseases known to predispose them to PAD.

Conclusion

In conclusion, the appearance of risk factors in an underserved high risk population identifies a significant percentage of individuals with peripheral arterial disease. The prevalence of 22.5% is higher than nationally reported given the average age of 46.03 years in this study. The sample population is much younger than currently studied and available in the literature for this disease process. Unlike all published studies on peripheral arterial disease, little data is known about the correlation of underserved populations and illicit drug use and the prevalence of PAD. Screening those at risk for PAD using the Doppler ABI assessment technique is non-invasive, inexpensive and well

tolerated. It is an important tool which can be utilized to reduce the risk of CVD and amputations and maintain quality of life.

Primary care nurse practitioners, providing services in the community to an underserved population, may have limited time and resources for adequate assessment and therapeutic intervention. Secondary and tertiary prevention strategies based on patient needs must incorporate education and health-promotion relative to the individual's personal values, according to Milio's framework (1976). Furthermore, the nurse practitioner must advocate for corporate and governmental policies that promote health and resources for all citizens.

APPENDIX A
DATA COLLECTION FORM

Patient's initials:	DOB:		Sex:	Race:
HTN Dx:	BP:		BP Med:	
HLIPID Dx:	Tchol:	Ldl:		Hlipid Med:
DM Dx:	Fbg:	HgbA1c:		DM Med:
Smoker:	Pack/year history			

PHYSICAL ASSESSMENT (Document presence/absence/characteristic)

Right foot/leg	Assessment Criteria	Left foot/leg
	Posterior tibialis pulse	
	Dorsalis pedis pulse	
	Low skin temperature	
	Hair loss	
	Capillary refill	
	Thickened toenails	
	Shiny/scaly skin	
	Lesion/ulcer/gangrene	
	Sensory perception	
	Edema	

ABI CALCULATION

	Doppler			Electronic BP		
Brachial systolic:	Right:	Left:		R:	L:	
Dorsalis Pedis:	R:	L:	ABI:	R:	L:	ABI:
Posterior Tibialis:	R:	L:	ABI:	R:	L:	ABI:
Take highest ankle systolic per leg/highest of both brachial systolic = ABI Ratio						

APPENDIX B

SAN DIEGO CLAUDICATION QUESTIONNAIRE

(INTERVIEWER ADMINISTERED VERSION)

			Right	Left
1) Do you get pain or discomfort in either leg or either buttock on walking?	**No**	**1**	**1**	
	Yes	**2**		**2**
	(If no, stop)			
2) Does this pain ever begin when you are standing still or sitting?	**No**	**1**	**1**	
	Yes	**2**		**2**
3) In what part of the leg or buttock do you feel it?				
a) Pain includes calf/calves	**No**	**1**	**1**	
	Yes	**2**		**2**
b) Pain includes thigh/thighs	**No**	**1**	**1**	
	Yes	**2**		**2**
c) Pain includes buttock/buttocks	**No**	**1**	**1**	
	Yes	**2**		**2**
4) Do you get it when you walk uphill or hurry?	**No**	**1**	**1**	
	Yes	**2**		**2**
	Never walks uphill/hurries			**3**
5) Do you get it when you walk at an ordinary pace on the level?	**No**	**1**	**1**	
	Yes	**2**		**2**

6) Does the pain ever disappear while you are walking?	**No**	**1**	**1**
	Yes	**2**	**2**
7) What do you do if you get it when you are walking?	**Stop or slow down**	**1**	**1**
	Continue on	**2**	**2**
8) What happens to it if you stand still?	**Lessened or relieved**	**1**	**1**
(If unchanged, stop)	**Unchanged**	**2**	**2**
9) How soon?	**10 minutes or less**	**1**	**1**
	More than 10 minutes	**2**	**2**

Answer Key

1) **No pain – 1=1**
2) **Pain at rest-1=2 and 2=2**
3) **Non-calf-1=2 and 2=1 and 3a=1 and 3b=2 or 3c=2**
4) **Non-Rose calf-1=2 and 2=1 and 3a=2, and not Rose**
5) **Rose-1=2 and 2=1 and 3a=2 and 4=2 or 3 (and if 4=3, then 5=2)**

And 6=1 and 7=1 and 8=1 and 9=1

APPENDIX C

AUTHORIZATION FOR USAGE OF SAN DIEGO CLAUDICATION QUESTIONNAIRE

Dr. Criqui,

I read with interest several articles you authored or co-authored on PAD. I am a nurse practitioner candidate at the University of North Florida and would like to possibly use the San Diego claudication questionnaire for a study which I will shortly begin. Will you please advise me how to get access and permission to use the questionnaire in my study? Thank you in advance for your help.

Laura M. Triola, MAS, RN

Hi Laura, Both interviewer and self administered versions attached. Feel free to use. MC

Michael H. Criqui MD, MPH

Professor and Vice-Chair

Dept. of Family and Preventive Medicine

Appendix D

UNIVERSITY OF NORTH FLORIDA
JACKSONVILLE, FLORIDA
HUMAN RESEARCH CONSENT FORM

TITLE: Peripheral arterial disease screening of a high-risk underserved population

INVESTIGATORS: Laura Triola, RN

AFFILIATIONS: University of North Florida School of Nursing
CONTACT INFORMATION: Laura Triola, RN 1209 Salt Creek Island Drive
Ponte Vedra FL 32082 904-273-1279
Deloris Irvin School of Nursing 904-620-2680

APPROVED BY INSTITUTIONAL REVIEW BOARD:

This is an important form. Please read carefully. It tells you what you need to know about this research study. If you agree to take part in this study, you need to sign this form. Your signature means that you have been told about the study and what the risks are. Your signature on this form also means that you want to take part in this study.

Your participation in this research is entirely voluntary. Refusal to participate in this research will involve no penalty or loss of benefits to which you otherwise are entitled.

You may discontinue participation in this research study at any time without penalty or loss of benefits you are otherwise entitled to.

What is the purpose of this study?

The purpose of this study is to determine the amount of Peripheral Arterial Disease (PAD) or severe leg problems, at this clinic.

How many participants will take part in this study?

We hope to enroll thirty-five to fifty participants will participate in this study.

What will happen in this study?

If you are able and choose to be in this study, your medical records will be reviewed to see if you have high blood pressure, high cholesterol, diabetes and history of smoking. You will be asked to answer some questions about your legs and if you have any pain when you walk or exercise. A brief examination of your legs and feet will be performed. Blood pressure readings in your arms and legs will be taken using two machines. An ankle-brachial index will be calculated from the blood pressure readings and will help determine your risk of PAD (severe leg problems).

How long will I be in the study?

The procedure described above will take approximately one hour and will be conducted over the next eighteen months to two years.

Are there reasons I might leave the study early?

Taking part in this study is your decision. You may decide to stop at any time. You should tell me if you wish to stop participation in the study or you may be asked to discontinue participation if it is in your best interest to do so.

What are the risks of the study?

There are no apparent risks to participation in this study. Some discomfort may occur while you are lying flat or when the blood pressure cuff is inflated (pumped up).

What happens if I am injured because I took part in this study?

No physical or emotional injuries are anticipated

(If more than minimal risk, will I be compensated if injured? Will medical treatment be provided? If so, what will it consist of? Where can I get further information on this matter?)

N/A

Are there benefits to taking part in this study?

Because this is a screening test, the results may indicate that you have a potential problem with circulation (blood flow) in your legs. If that happens, we will help you get an appointment for follow-up treatment.

What other choices do I have if I do not take part in this study?

You may continue to receive your regular medical care.

Are there any monetary or other compensation or inducements for my taking part in this subject?

None.

Are there any financial costs to me to take part in this study?

If you are referred to medical care for follow-up based on the screening, that care will be paid the same way as if you were not participating in the study.

What are my rights if I take part in this study?

You do not have to take part in this study; but if you do, you can stop at any time. You will be told of important new findings or any changes in the study or procedures that may affect you. You do not give up any of your rights by taking part in this study.

What about confidentiality?

Data from this study may be published or used in publications. However, your name and other identifying information will not be sent outside of UNF without written permission unless the law allows it.

EXPLAIN YOUR METHOD FURTHER

The ankle-brachial index involves using a blood pressure cuff and special stethescope to take your blood pressure in each arm and each ankle. From this a number is calculated indicating your risk for PAD (severe leg problems).

Will there be audiotaping or videotaping? If so, will I get to view them before they are used? Who will review tapes besides the researchers? Who will have access to the tapes? When will they be destroyed?

(Note – If tapes are to be used outside of the research project, a separate release form should be obtained.)

No videotaping or audiotaping will be included in this study.

Who can answer my questions?

You may talk to Laura Triola, RN at any time about questions and concerns you may have about this study. You may contact Laura Triola, RN at the University of North Florida School of Nursing, (904) 620-2685. You may also call Dr. Jan Meires, faculty mentor at 620-1469.

You may get further information about UNF policies, the conduct of this study, the rights of research subjects or if you suffer injury related to your participation in this research project from the Institutional Review Board Chairperson, Dr. Kathalcen Bloom, at (904) 620-2685.

I have had an opportunity to have my questions answered. I have been given a copy of this form. I agree to take part in this study. I am over 18 years of age.

I am at least 18 years old. _____ (initials)

I have had the study that I am agreeing to participate in explained to me to my satisfaction. _____ (initials)

I have had the opportunity to ask any questions that I may have had regarding this study.

_____ (initials)

I agree to participate in *(study name)* Peripheral arterial disease study ____ being conducted by ***(PI)*** **Laura Triola, RN** and the University of North Florida.

_____ _____

Date Printed Name of Participant

_____

Signed Name of Participant

_____ _____

Date Printed Name of Individual Obtaining Consent

_____ _____

Date Signed Name of Individual Obtaining Consent

APPENDIX E

Consent to Participate in Research Script

You have been asked to participate in a study.

Purpose: The purpose of this study is to find out how many residents have severe leg problems or peripheral arterial disease (PAD).

Duration: The study will be conducted over an 18-month period. You will be asked to undergo a physical exam and answer a questionnaire that will take about two hours of your time.

Procedure: If you agree to participate, you will:

1) Be asked questions about your health.
2) Have a physical exam taken of you legs and feet.
3) Answer a nine-item questionnaire.
4) Have blood pressure readings taken of your arms and legs using two different machines.

Eligibility: A resident is able to participate if he or she has any of the following conditions.

1) High blood pressure (hypertension)
2) High blood sugar (diabetes)
3) High blood fats (hyperlipidemia)
4) History of smoking

We hope to enroll 35-50 participants in this study.

Risks: There are no known risks to participation in this study.

Benefits: This screening tool will help to identify a severe leg problem.

Alternative Care: Participation in this study is totally voluntary. If you decide not to participate in this study you will continue to receive care at the medical clinic as you did previously.

Confidentiality: All records will be kept confidential. No publications will contain specific patient information. Your identity will not be disclosed.

If you have any questions or concerns, please contact me, Laura Triola, RN at 904-273-1279 or Dr. Jan Meires at the University of North Florida 904-620-1469.

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Vita

Laura Walter Triola was born in Belfonte, Pennsylvania on January 3, 1960. She has a Bachelor of Science in Nursing from University of Maryland, 1983 and a Masters of Administrative Sciences from the Johns Hopkins University, 1988. She received a Masters of Science in Nursing from the University of North Florida, April 2006. Dr. Jan Meires of the University of North Florida is serving as Laura's thesis advisor. Laura currently practices clinical nursing in Northeast Florida. Prior to that, Laura worked at Northeast Florida Plastic Surgery as a primary care surgical nurse and quality assurance manager and as a neonatal intensive care nurse at the University of Maryland Medical Systems in Baltimore, Maryland.

Laura's interests are in health promotion and disease prevention in family practice. She particularly enjoys providing services to underserved populations. Laura is a member of Hands Healing Hearts, a nonprofit organization that provides medical care as well as plastic and reconstructive surgery to children and adults in third world countries. Her article entitled *How to deal with dental emergencies* was published in The Clinical Advisor, December 2005. Married for 17 years, Laura is the mother of two teenage sons.