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Risk Factors for Peripheral Artery Disease-Related Amputations Among Black Americans

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This is to certify that the doctoral study by

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has been found to be complete and satisfactory in all respects,
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Walden University
2025

Abstract

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Doctoral Study Submitted in Partial Fulfillment

of the Requirements for the Degree of

Doctor of Public Health

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February 2025

Abstract

Evidence suggests that Black Americans (BAs) are at a significantly higher risk of peripheral artery disease (PAD)-related amputations. This study aimed to examine risk factors for non-traumatic lower extremity amputation (NTLEA) among BAs with PAD addressing a significant knowledge gap regarding racial disparities in PAD outcomes. Grounded in Bandura's social cognitive theory, which posits the interplay among personal factors, environmental influences, and behavior, this study examines how age, gender, income, and comorbidities like cardiovascular disease, kidney disease, and diabetes influence NTLEA across various insurance types (private, Medicaid, Medicare, self-pay). This quantitative cross-sectional study used the 2020 National Inpatient Sample, 1% of which were BAs with PAD (n = 9,731). Of these, 2,140 underwent NTLEA. Logistic regression showed significant disparities. Women were less likely to experience NTLEA than men (OR = 0.60, 95% CI: 0.54-0.66, $p < 0.001$). Kidney disease (OR = 1.19, 95% CI: 1.08–1.32, $p = 0.001$) and diabetes mellitus (OR = 6.73, 95% CI: 1.21–37.52, $p = 0.030$) increased the risk of NTLEA while age had no significant effect on NTLEA. Health insurance type modified the associations: private insurance increased NTLEA odds among those with kidney disease (OR = 2.39, 95% CI: 1.2–4.77, $p = 0.014$), while Medicare decreased it for those with cardiovascular conditions (OR = 0.67, 95% CI: 0.51-0.88, $p = 0.004$). These findings highlight the urgent need to reevaluate healthcare policies and interventions to mitigate disparities. Findings can be used to create tailored healthcare solutions based on insurance type and comorbidity profiles to foster positive social change and promote equitable health outcomes for BAs with PAD.

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Dedication

This study is dedicated to my beloved eldest brother, David Braynen Jr., whose life was tragically cut short by kidney disease while I was in the midst of my research. Thank you for always cheering me on; your memory inspires me daily. I also dedicate this work to my mother-in-law, who bravely endured the debilitating effects of peripheral artery disease, diabetes, and other comorbidities, ultimately leading to a lower extremity amputation. Tragically, she passed away within the first year following this life-altering procedure, leaving a profound void in our lives. I miss you both dearly.

To all the amputees I have met, loved, and lost during my decade-long journey working in the field of prosthetics, your positivity, smiles, resilience, and strength have profoundly shaped my life and work. I remain steadfastly committed to improving health literacy and access to care, striving to ensure that others can live longer, healthier lives, free from the premature losses that have affected my family and countless others. Your stories fuel my passion and dedication to advancing care, advocating for equitable healthcare, and making meaningful differences in the lives of those I serve.

Acknowledgments

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I extend my deepest appreciation to Dr. Hebatullah Tawfik and Dr. Jennifer Gadarowski, my research committee chairpersons, for their dedication, invaluable support, and constructive feedback. Your guidance has been instrumental in driving this process to completion, and I am truly grateful for your expertise and mentorship.

I would also like to acknowledge my extended family and friends who have stood by me during this long and exhausting journey. Your prayers, encouragement, and unwavering support have meant the world to me. Thank you for believing in me and helping me stay focused on my goals.

This accomplishment is not just mine; it is a reflection of the collective support I have received. I am deeply grateful to each of you for being an integral part of my journey.

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Section 1: Foundation of the Study and Literature Review

Introduction

Evidence suggests a connection between peripheral artery disease (PAD) and a heightened risk of cardiovascular morbidity, amputation, and mortality (McGinigle, 2024). PAD is a prevalent and incapacitating presentation of cardiovascular illness that hinders the circulation of blood to the lower limbs. According to Barnes et al. (2020), PAD affects about 8.5 to 12 million Americans, which is approximately 25% higher than in the previous decade. Black American (BA) patients are at a significantly higher risk of PAD-related amputations, and the incidence is two times higher than it is in Whites and Hispanics (Barnes et al., 2020; Garcia et al., 2019). This may suggest a possibility to reduce the risk of amputation by understanding the risk factors associated with PAD-related amputations.

Amputation is a devastating, yet preventable, complication commonly associated with advanced PAD, known as chronic limb-threatening ischemia (CLTI) (McGinigle, 2024). The signs and symptoms of PAD can appear relatively late in life. For many individuals, these will not appear until the artery has narrowed by 60% or more, causing CLTI (Matsushita et al., 2019). CLTI affects more than 2 million people in the United States and is associated with increased amputation risks (McGinigle, 2024). Due to poor management of the CLTI, amputation is often considered a marker for inadequate intervention of cardiovascular disease (CVD) (McGinigle, 2024). Amputation is also associated with poor quality of life and death related to cardiac complications (McGinigle, 2024). According to McGinigle (2024), up to 74% of CLTI patients who undergo limb amputations die after 5 years owing to cerebrovascular complications. Due to the complications associated with advanced PAD (CLTI) leading to amputations, exploring the predisposing risk factors in this population is imperative to avert the adverse effects.

Epidemiological research has consistently highlighted the disproportionate impact of PAD on Black Americans (BAs). Bryce et al. (2022) reported that nearly 3 million BAs between ages 50 and 79 are affected by PAD, with BAs and Hispanics experiencing approximately twice the amputation rates compared to other populations. Consistent with these findings, Barnes et al. (2020) confirmed the elevated amputation risk among BAs with PAD. Given these disparities in PAD prevalence, this study aims to investigate the comprehensive risk factors associated with PAD-related amputations in this demographic group.

Problem Statement

The problem necessitating the current study is that it is not known to what extent specific demographics, comorbidities, access to health insurance, and the type of insurance influence the occurrence of PAD-related amputations in BAs and to what degree health insurance status may modify the association between comorbidities and nontraumatic lower extremity amputation (NTLEA) among BAs with PAD. Researchers have indicated that PAD prevalence among people age 40 or above has increased from 4% to 12% in the last 3 years (Behroozian & Beckman, 2020). Garcia et al. (2019) attributed escalating PAD occurrences to an increasing aging population, and Hackler et al. (2021) identified diabetes as a significant contributor to heightened PAD prevalence.

Moreover, researchers have indicated that the prevalence of PAD in individuals age 40 years and above currently stands at around 4.3% but increases to almost 15% in those age 70 years and above (Minc et al., 2021).

Surprisingly, BAs have rates of PAD that are twice as high as other ethnicities for any given age over 40 (Hackler et al., 2021). The underdiagnosis and undertreatment of PAD in the general population, particularly among Black or African American (AA) individuals, may indicate a potentially greater disparity than previous documentation suggests. The effects of PAD on BAs are disproportional, given that members of this population face high levels of lower extremity amputation owing to the prevalence of the disease (Garcia et al., 2019).

Researchers have explored demographic factors such as geographical location in relation to PAD, finding that high-income countries like the United States and the United Kingdom exhibit higher PAD rates than low- and middle-income countries (Anjum et al., 2021). The association of gender with PAD has also been investigated, with Patel et al. (2020) noting an accelerating prevalence in women, especially in low- and middle-income countries. Additionally, Patel et al. (2020) observed that PAD is more prevalent in men, with an increasing occurrence beyond the age of 40. However, there is limited research examining the potential impact of modifiable risk factors such as access to health insurance and the type of insurance on the occurrence of PAD-related amputations. These modifiable risk factors include their influence on demographic characteristics (such as median household income, gender, and age) and comorbidities (such as CVD, kidney disease, and diabetes mellitus), particularly among Black or AA individuals.

Purpose of the Study

This quantitative retrospective cross-sectional study aimed to investigate the correlation between independent variables such as age, gender, median household income, comorbidities (CVD, kidney disease, diabetes mellitus), health insurance status (private insurance, Medicaid, Medicare, self-pay), and the occurrence of the dependent variable—PAD-related amputations in Black or AA individuals. Furthermore, the study seeks to determine whether health insurance influences the association between comorbidities and PAD-related amputations. As indicated by Garcia et al. (2019), BAs are more likely to have PAD and for cases to be more severe and have worse outcomes than other races and ethnic groups. Moreover, Bryce et al. (2022) identified significant PAD disparities among BAs and associated these disparities with increased PAD-related amputations.

Research Questions and Hypotheses

The study will be guided by the following research questions and hypotheses.

RQ1: Is there an association between demographics including median household income, gender, and age, and the occurrence of NTLEA among BAs diagnosed with PAD?

$H_0$1: There is no association between median household income, gender, and age and the occurrence of NTLEA among BAs diagnosed with PAD.

H_A1: There is an association between median household income, gender, and age and the occurrence of NTLEA among BAs diagnosed with PAD.

RQ2: Is there an association between health insurance status (private insurance, Medicaid, Medicare, self-pay) and the occurrence of NTLEA among BAs diagnosed with PAD while controlling for age, median household income, and gender (confounders)?

$H_0$2: When age, median household income, and gender are controlled, there is no association between health insurance status (private insurance, Medicaid, Medicare, self-pay) and the occurrence of NTLEA among BAs diagnosed with PAD.

H_A2: When age, median household income, and gender are controlled, there is an association between health insurance status (private insurance, Medicaid, Medicare, self-pay) and the occurrence of NTLEA among BAs diagnosed with PAD.

RQ3: Is there an association between comorbidities (namely CVD, kidney disease, and diabetes mellitus) and the occurrence of NTLEA among BAs diagnosed with PAD while controlling for age, median household income, and gender (confounders)?

$H_0$3: When age, median household income, and gender are controlled, there is no association between comorbidities (namely CVD, kidney disease, and diabetes mellitus) and the occurrence of NTLEA among BAs diagnosed with PAD.

H_A3: When age, median household income, and gender are controlled, there is an association between comorbidities (namely CVD, kidney disease, and diabetes mellitus) and the occurrence of NTLEA among BAs diagnosed with PAD.

RQ4: Is there an effect modification of the association between comorbidities (CVD, kidney disease, and diabetes mellitus) and NTLEA among BAs diagnosed with

PAD by health insurance status (private insurance, Medicaid, Medicare, self-pay) while controlling for age, median household income, and gender (confounders)?

$H_0$4: When age, median household income, and gender are controlled, there is no effect modification of the association between comorbidities (CVD, kidney disease, and diabetes mellitus) and NTLEA among BAs diagnosed with PAD by health insurance status (private insurance, Medicaid, Medicare, self-pay).

H_A4: When age, median household income, and gender are controlled, there is an effect modification of the association between comorbidities (CVD, kidney disease, and diabetes mellitus) and NTLEA among BAs diagnosed with PAD by health insurance status (private insurance, Medicaid, Medicare, self-pay).

Theoretical Framework: Social Cognitive Theory

The foundational theoretical framework for this study is Bandura’s (1986) social cognitive theory (SCT), which illustrates the impact of individual internal and external social experiences and factors that influence health outcomes. Since its development, applications of SCT have expanded significantly to inform explanations of human behavior in diverse settings and contexts (Luszczynska & Schwarzer, 2015). SCT explains the cause of human behaviors based on reciprocal interactions and influences from personal/cognitive, behavioral, and environmental factors (Bandura, 1986). Interactions between and influences from these factors can vary considerably based on context. Additionally, these factors and interactions between factors evolve based on individuals’ experiences, creating the possibility of new outcomes and degrees of satisfaction with the outcomes achieved through one’s actions. In this regard, the theory will explain the complex associations and the effect modification between individual-level risk factors, including gender, age, and comorbidities, and external risk factors, such as income and access to health insurance. Moreover, this study will illustrate the links between these factors and the occurrence of NTLEA among BAs diagnosed with PAD.

SCT was the framework utilized in prior research on PAD and its association with amputations, primarily exploring self-efficacy's role in managing the disease (F. C. Tan et al., 2021). Also, Glanz et al. (2015) stipulated that SCT may provide insights into the personal and environmental factors shaping self-efficacy, including social support, cognitive processes, attitudes, and beliefs (Martos-Méndez, 2015). In the context of amputations related to PAD among BAs, the theory offers a valuable framework for understanding the factors contributing to disease complications among the observed population. Studies have indicated that BAs are disproportionately affected by PAD and the associated amputations (Arya et al., 2023; Eid et al., 2021; Fereydooni et al., 2023; Mustapha et al., 2017). As reported by Arya et al. (2023), Black or AA individuals are twice as prone to experience PAD and are four times more susceptible to undergo amputation compared to White Americans. In this regard, Fereydooni et al. (2023) indicated that the increased risk is associated with traditional risk factors putting BAs at a disadvantage, including higher rates of Type 2 diabetes, use of tobacco, and high blood pressure, significantly associated with the disparities in socioeconomic status.

Arya et al. (2023) also noted that despite adjusting for the traditional risk factors, BAs still reported a higher prevalence of PAD than Whites, suggesting other factors might be involved. Applying SCT to the relationship between demographics and NTLEA among BAs diagnosed with PAD, demographic variables such as household income, gender, and age disparities can be viewed as social factors influencing health behaviors and outcomes. Thus, the theory's relevance to understanding the relationship between demographics and the occurrence of NTLEA among BAs diagnosed with PAD, including differences in health utilization, health access, genetics, and lifestyle factors (Li et al., 2022). Overall, the rationale for the application of SCT is on the framework's ability to account for the complex interplay between behavioral, individual, and environmental factors contributing to health outcomes, relevance in explaining self-efficacy in the management of PAD, and application of the theory to the health disparities and outcomes research, particularly concerning ethnicity and race.

Nature of the Study

I used a quantitative methodology with a retrospective, cross-sectional research design to carry out a multilevel observation of the risk factor demographics (i.e., median household income, gender, and age), comorbidities (CVD, kidney disease, and diabetes mellitus), health insurance access and type of health coverage, and the effect modification of the association between comorbidities (CVD, kidney disease, and diabetes mellitus) and NTLEA among BAs diagnosed with PAD by health insurance status (private insurance, Medicaid, Medicare, self-pay). For this study, the 2020 National Inpatient Sample (NIS) data set from the Agency for Healthcare Research and Quality (AHRQ) will be analyzed retrospectively to help determine the association between age, gender, median household income, comorbidities, health insurance status, and PAD-related amputations in BAs, and whether it is a modification of the association between comorbidities and NTLEA by health insurance.

Literature Search Strategy

To locate literature from past studies, I searched sources from various libraries and databases, including PubMed, MEDLINE, Embase, CINAHL, and Google Scholar. To search for the literature, I used the following terms singularly or in combination using Boolean operators: *peripheral artery disease (PAD), PAD-related amputations, amputation risk factors, ethnicity and PAD amputations, cardiovascular risk factors, diabetes and PAD, hypertension and PAD, obesity and peripheral artery disease, atherosclerosis in Black population, socioeconomic factors and amputation, obesity and peripheral artery disease*, and *peripheral vascular disease*. Of the selected and reviewed sources, 86% were published between 2018 and 2023, while the rest included a few seminal sources relating to Bandura's SCT and self-efficacy. Including recent sources ensures that the review captures the latest literature and identifies existing gaps that require further exploration.

Literature Review

Peripheral Artery Disease and Amputations

PAD is a health condition characterized by the blockage or narrowing of the arteries that supply blood to the limbs, resulting in reduced blood flow and tissue damage (Campia et al., 2019). According to Barnes et al. (2020), PAD has become a prevalent condition affecting approximately 8.5 million people in the United States alone. The vulnerability to PAD increases with age, affecting over 15% of adults over 70 (Hackler et al., 2021). Researchers have posited that PAD is more common in men than in women and is more prevalent in BAs and Hispanics than non-Hispanic Whites (Arya et al., 2023; Fereydooni et al., 2023; Hackler et al., 2021; Mustapha et al., 2017; Sheen et al., 2018; Tarricone et al., 2023). According to Campia et al. (2019), the risk factors for PAD are similar to those of other CVDs, including smoking, age, family history, hyperlipidemia, diabetes mellitus, and hypertension. Other factors include obesity, chronic kidney disease, and physical inactivity (Raja et al., 2021). Barnes et al. (2020) also posited that the severity of PAD symptoms depends on the severity of the condition and may include claudication, gangrene, non-healing wounds, and rest pain.

Furthermore, research has established a connection between PAD and diabetes mellitus, where diabetes serves as a substantial risk factor for PAD development (Matsushita et al., 2019). Individuals diagnosed with diabetes mellitus are also at a heightened risk, being two to four times more likely to develop PAD compared to those without diabetes (Kamil et al., 2019; Soyoye et al., 2021). Moreover, individuals with both PAD and diabetes mellitus face a significantly increased risk of developing conduit artery occlusive disease, leading to amputations, compared to those with either condition alone. However, Cecchini et al. (2022) noted that PAD is associated with many risks, and limited modeling research comprehensively outlines the various risks associated with this condition. PAD has remained a serious public health problem globally, and there is a need to explore different risk factors (Lin et al., 2022).

Nontraumatic Lower Extremity Amputation

NTLEA refers to the surgical removal of a portion of the entire limb, such as the leg, ankle, or foot, due to a medical condition or disease (Liao et al., 2022). NTLEA is a severe condition that leads to significant emotional and physical effects. According to Behroozian and Beckman (2020), NTLEAs are associated with PAD and its concurrent health conditions. Research estimates that over 185,000 amputations are performed in the United States related to lower limb amputations. Among these, 60% are PAD-related, and over 80% involve the lower limbs. Harding et al. (2020) reported a 13% higher prevalence of NTLEA among individuals with PAD. Behroozian and Beckman (2020) suggested that NTLEA has been recognized as a substantial public health challenge, resulting in diminished ambulatory independence, decreased quality of life, and a reduction in life expectancy.

Moreover, Garcia et al. (2019) stipulated that nontraumatic lower limb amputation represents a severe complication of diabetic neuropathy and peripheral vascular disease. Tarricone et al. (2023) noted that NTLEA is associated with chronic illnesses, such as diabetes mellitus and PAD, which account for 50% of the cases. Scholars have made efforts to study the risk factors associated with NTLEA, especially with PAD, which accounts for a 9-fold increase in the risk level, and diabetes, which accounts for a 30-fold increase in risk (Tarricone et al., 2023). However, limited modeling work explores the relationship between PAD, NTLEA, and all other risk factors, which led to Cecchini et al. (2022) recommending more work in this area.

Demographic Factors and the Occurrence of NTLEA

NTLEA is a significant public health concern in the United States, particularly among individuals with PAD. Researchers have investigated the relationship between demographic composition and NTLEA incidence rates, including demographic factors such as age, gender, household income, race, and ethnicity. According to Garcia et al. (2019), understanding the demographic composition of populations at risk of NTLEA essentially assists in developing targeted public health interventions to reduce nontraumatic lower limb amputation incidences. Alterations in demographic composition and decreased smoking rates have been linked to a decline in NTLEA incidence rates. However, these reductions were surpassed by elevated rates of diabetes, PAD, and chronic kidney disease (Hughes et al., 2019). Consequently, individuals with low socioeconomic status are more likely to develop NTLEA-associated complications (Tarricone et al., 2023). By studying specific demographic groups and risk factors potentially impacting NTLEA, will allow public health interventions to target BAs effectively, address the underlying risk factor for lower extremity amputations and help prevent the development of severe PAD conditions.

Median Household Income

Studies have reported on the association between low household income and increased risk of NTLEA complications, with a shared perspective among researchers that socioeconomic status may be a pivotal factor influencing the risk factors associated with NTLEA (Arya et al., 2023; Bernatchez et al., 2021; Fereydooni et al., 2023). According to Hackler et al. (2021), NTLEA is prevalent in areas characterized by lower socioeconomic status, median household incomes of $40,000 or below, elevated neighborhood poverty, and higher area deprivation indices. In a preliminary study by Eslami et al. (2007), households with low median income and those living in low-income neighborhoods experienced a 2.4% higher vulnerability to NTLEA complications than those in higher-income home neighborhoods. Similarly, Westlund (2021) found that low-income individuals in Sweden experienced high NTLEA risks compared to high-income individuals, even after adjusting for race, sex, education, and other comorbidities. As Minc et al. (2021) indicated, significant shifts in demographics across the United States, marked by median household income declines of approximately 1.2%, have been accompanied by increases in NTLEA occurrences.

Hughes et al. (2019) stipulated that several factors determine the relationship between household income and NTLEA, including limited access to care and poor nutrition. As discussed, low-income households are less likely to access health insurance, limiting preventive care mediating the development and progression of NTLEA health risks (Garcia et al., 2019; Sheen et al., 2018). Moreover, Tayyem et al. (2022) posited that low-income households have limited access to proper nutrition, contributing to obesity, a risk factor for diseases associated with NTLEA.

Race and ethnicity are also essential factors when investigating the relationship between household income and NTLEA incidence rates. Studies in the United States indicated that racial and ethnic minorities have a higher prevalence of comorbidities related to complications leading to the development and progression of NTLEA (Fereydooni et al., 2023; Johnson & Louis, 2022; Matsushita et al., 2019). For instance, Eid et al. (2021) and Matsushita et al. (2019) indicated that BAs, Native Americans, and Hispanic Americans report a higher rate of diabetes, a leading contributing factor to the occurrence of NTLEA, than non-Hispanic White Americans. Moreover, studies on geographic racial and ethnic distribution in the United States show that ethnic minorities are likelier to live in low-income neighborhoods, contributing to a higher prevalence of NTLEA complications.

Despite studies showing that household income is a risk factor contributing to PAD and NTLEA (Criqui et al., 2021), there lacks a comprehensive study that explores the contribution coefficients of the different potential independent variables in a single study on the U.S. population. Further, Tarricone et al. (2023) recommended further research to explore the various risk factors that can be used in assessing and screening the PAD and its contributory role in NTLEA. It is also important to understand the effect modification between risk factors and health insurance status on the occurrence of NTLEA among BAs diagnosed with PAD (Hackler et al., 2021).

Gender

Research literature into the association between gender and NTLEA incidence rates posits a higher prevalence rate in women than men (Tarricone et al., 2023). Preliminary data from the study on the Global Burden of Disease indicated that compared to men, women experienced a higher increase in NTLEA, leading to PAD-related deaths and disability (Sampson et al., 2014). Srivaratharajah and Abramson (2018) argued that one of the reasons for the difference is that women tend to seek healthcare services at advanced stages of PAD more than men, reflected in the higher mortality rates and adverse PAD outcomes, including NTLEA. The research attributed the delays to the general misconception that PAD is predominant in men and that women have higher atypical, subclinical, and asymptomatic PAD (Srivaratharajah & Abramson, 2018). Thus, despite the global decline in the burden of age-standardized death rates from NTLEA, women continue to experience poorer health outcomes (Jelani et al., 2018). In this regard, Chase-Vilchez et al. (2020) posited that the American Heart Association and Vascular Disease Foundation advocated for an intervention campaign urging health professionals to screen women at risk of PAD promptly and to develop women-specific health education about PAD.

Pabon et al. (2022) stated that biological factors might play essential roles concerning increased rates of peripheral vascular disease in men and the interplay of gender and cardiac mortality in women. The biological-based differences in the manifestation of NTLEA may be linked to sexual dimorphism (two sexes of the same species exhibiting different characteristics, which may include size, weight, or behavioral traits) of the health vascular substrate and variations in the responses to vascular stressors (Pabon et al., 2022). Recent research by Kavurma et al. (2023) robustly affirmed earlier studies, highlighting discernible gender variations in NTLEA, with a higher prevalence observed in women and poorer health outcomes reported for women. Even so, Pabon et al. (2022) shared that there are still mixed results in studies examining PAD outcomes among male and female genders, likely due to the complexity of sex-specific pathophysiological and risk factor interactions. Hence, additional efforts are needed to understand better sex-based differences in PAD development to achieve improved outcomes among this vulnerable population.

Age

Further, studies have shown the prevalence of the association between age and risks of NTLEA (Harding et al., 2020; Tarricone et al., 2023). Age-related health conditions such as chronic kidney disease, PAD, and diabetes significantly mediate the development of NTLEA. Therefore, as people age, the risk of developing associated conditions increases the risk of NTLEA. N. Walter et al. (2022) indicated that increasing age is a crucial risk factor in major NTLEAs, including exarticulation of the hip and transfemoral amputation. Harding et al. (2020) stated that increased rates of NTLEA are most pronounced among those age 75 and older. Even so, there are disparities in the amputation risk, which can make it challenging to reduce PAD-related NTLEA among high-risk groups such as BAs (APHA, 2021). The pathway ahead will require the study of patients at the most significant risk where amputation rates remain unacceptably high. Additional research on the complex interactions and effect modification of independent and confounding risk factors, such as age, within high-risk populations of amputation will provide a clearer vision.

Health Insurance Status and the Occurrence of NTLEA

NTLEA frequently constitutes a costly and devastating complication, resulting in the loss of ambulatory status, permanent disability, and a decline in functional capabilities. This may be linked to a decrease in overall quality of life (Creager et al., 2021). Researchers have explored the association between health insurance status and the occurrence of NTLEA. For instance, Barnes et al. (2020) stated that PAD patients with Medicaid health insurance face increased risks of undergoing amputation. Similarly, a preliminary study by Eslami et al. (2007) presented similar findings indicating a higher prevalence of primary amputations in patients without private insurance and those with Medicare or Medicaid insurance.

Moreover, Hughes et al. (2019) examined the effect of income on the incidence rates of significant leg amputations and concluded that uninsured individuals face the highest risk of lower extremity amputations compared to those with government-funded or private insurance beneficiaries. Therefore, the associated costs limit access to care, especially for uninsured individuals, and access to resources and specialized professions for individuals insured under Medicaid or Medicare programs (Yuan et al., 2018). The reasons for the association between health insurance and NTLEA are multifactorial, and it is not clear if this is a linear relationship due to the health insurance status or modification effect caused by other risk factors (Hughes et al., 2019). Hence, this study was conducted to identify whether insurance accessibility and the effect modification between risk factors and health insurance status influence NTLEA among BAs diagnosed with PAD.

Comorbidities and the Occurrence of NTLEA

According to N. Walter et al. (2022), the risk of NTLEAs rises significantly in individuals with comorbidities, particularly those with PAD, where there is a notable 9% increase. Comorbidities associated with NTLEA encompass conditions such as diabetes, hypertension, ischemic heart disease, congestive heart failure, chronic kidney disease, and stroke (Biscetti et al., 2021). These conditions increase the risk of PAD and the subsequent NTLEA; consequently, managing these prevailing conditions promotes the management of PAD and the subsequent NTLEA health outcomes.

Further, chronic kidney disease is associated with an increased vulnerability to CVDs, among them PAD. According to Serra et al. (2021), the risk of PAD is almost seven times higher in patients with chronic kidney diseases than those without chronic kidney disease. Even though PAD and chronic kidney diseases share similar predisposing factors, studies indicate that their co-existence is not simply an association, but chronic kidney diseases represent a crucial independent risk factor for PAD development (N. Arinze et al., 2019). In the United States, Saran et al. (2017) examined data from the Medicare database and found a 24% higher prevalence of PAD in patients with chronic kidney diseases. The effect of the high prevalence of chronic kidney disease in patients with PAD is the association between NTLEA, mortality, and higher healthcare costs. For instance, Zlatanovic et al. (2018) stipulated that one quarter of patients hospitalized with PAD have chronic kidney disease incurring a 15% increase in healthcare expenses related to a 21% increase in hospital stay.

The need to investigate drivers of PAD disparities due to race is imperative to reduce PAD-related NTLEA and premature death. Further study is required to examine the association of comorbidities and health insurance access and type on the rate of PAD-related amputation.

PAD Risk Factors and Amputation

The risk factors for PAD-related amputations can be classified into nonmodifiable and modifiable factors. Nonmodifiable factors include race, gender, and age, while modifiable factors include lifestyle-related variables, including underlying medical conditions such as hypertension, CVD, diabetes, and kidney disease (Selvin & Erlinger, 2004). Another modifiable risk factor for PAD is physical inactivity, potentially leading to obesity and associated comorbidities, including hypertension, diabetes, and cardiovascular conditions (Haas et al., 2012; Parmenter et al., 2015). According to X. Wan et al. (2023), patients with associated comorbidities such as diabetes mellitus, hypertension, and CVDs are at a higher risk of PAD-related adverse NTLEs due to increased incidence of PAD, accelerating disease progression, and increased disease severity.

PAD and NTLEA remain a serious public health concern with considerable heterogeneity in determinants across sex, age, income, region, and race (Lin et al., 2022). Mustapha et al. (2017) emphasized that efforts to improve the quality of care for those with PAD and prevention strategies for PAD must focus on the subgroups at high risk for amputation. A better understanding of the association between modifiable PAD risk factors and amputation can help improve prevention strategies and reduce the burden.

Definitions

Amputation: Surgery to remove all or part of a limb for individuals who have a severe health condition like PAD (Patel et al., 2020).

Black Americans/African Americans: An ethnic group comprising Americans with partial or full ancestry from any of the Black racial groups of Africa (Patel et al., 2020).

Peripheral arterial disease (PAD): An ailment that is characterized by the buildup of fatty deposits in the leg or arm arteries, causing reduced blood flow (Anjum et al., 2021).

Assumptions

This study was a correlational study whose conclusions were founded on the regression results of the various variables. As such, various assumptions were made. It was assumed that the observations made concerning the various relationships would be independent of each other, which means that the value of the dependent variable for one observation is not influenced by that of the other observation. As it relates to homoscedasticity, it was assumed that the variance of the residuals would be constant across all the independent variables' levels to ensure a consistent spread of the residuals (see Chen et al., 2018). I also assumed there was no multicollinearity, indicating that the independent variables should not be correlated to each other. The assumption of multicollinearity helps to ensure the individual effects of the independent variables are isolated and identified (Gokmen et al., 2022). Finally, the assumption on endogeneity indicates that no variable or other form of endogeneity is omitted that could cause biased coefficient estimates.

Scope and Delimitations

The study is interested in PAD-related amputations, especially among BAs and not any other disease or demographic group. Further, the focus is on the following independent variables: age, gender, median household income, comorbidities (CVD, kidney disease, diabetes mellitus), health insurance status (private insurance, Medicaid, Medicare, self-pay), and PAD-related amputations in BAs as the dependent variable. Data were collected and used from NIS for this cross-sectional study that did not use primary data.

Limitations

For this study, archival data were used to analyze the relationship between the dependent and independent variables. The use of archival data has several advantages, yet it also has some limitations. First, the completeness and quality of the data are not guaranteed since the data were recorded in the past and could have errors, missing values, and inconsistencies that may affect reliability (Church, 2002). Secondly, while the data focused on the Black American population, archival data may present only some of the population of interest (Church, 2002). The selected data may be biased, which may affect the generalization of the findings to the entire Black American population. Archival data may not contain all the variables that the research requires, which could limit the ability to control confounding variables or the ability to understand the existing relationship.

Moreover, the study may be limited by endogeneity. Endogeneity may occur where there exists a bidirectional relationship between the independent and dependent variables. In this study, primary data were not collected, which may limit the ability to address the endogeneity issues since some of the variables may not be observed or may be omitted in the study (Barnes et al., 2020).

Significance

This study addresses NTLEA, a public health concern that has resulted in a significant financial burden to society and the healthcare system and reduces an individual's quality of life, physical mobility, and life expectancy (Creager et al., 2021). PAD has a negative impact on societal productivity. Due to reduced mobility caused by PAD ischemia, which includes pain during rest, gangrene, infections, and sores from a lack of blood flow to the legs, people with PAD experience increased complications managing their daily routine (Campia et al., 2019). Therefore, this study may lead to improved quality of life for both people and society by lowering the prevalence of PAD. In addition, PAD is strongly associated with other chronic conditions, such as diabetes, high blood pressure, ulcers, amputations, and necrosis (Lin et al., 2022; Matsushita et al., 2019; Mukherjee & Eagle, 2010; Serra et al., 2021). The complications brought on by PAD-related NTLEA substantially increase the risk of mortality and morbidity in the population.

Addressing the issue of PAD can help improve the population's quality of life and enhance productivity. PAD adversely affects productivity in society. Individuals diagnosed with PAD experience increased complications managing daily routine due to reduced mobility associated with PAD ischemia, including pain during rest, gangrene, infections, and sores from lack of blood flow to the legs (Eid et al., 2021). Thus, by reducing the prevalence of PAD, individuals' and society's quality of life can be improved. The management of PAD will also have good health effects on the prevalence of chronic illnesses in society, such as diabetes, improving the outlook for healthcare outcomes (Conte et al., 2019). This is because PAD is associated with several chronic disorders. Disparities seriously hinder society's growth and development, particularly regarding health outcomes. The results of the current study will provide insight into the risk factors associated with PAD for BAs.

Social Change

PAD-related NTLEAs are a public health concern that has resulted in a significant financial burden to society and the healthcare system and reduces an individual's quality of life, physical mobility, and life expectancy (Creager et al., 2021). In addition, PAD-related NTLEA is twice as likely to affect minorities such as BAs and Hispanics than Whites, emphasizing healthcare disparity (Mustapha et al., 2017). According to Demsas et al. (2022), PAD adversely affects society by contributing to adverse health outcomes, reduced functionality and quality of life, and the disease burden of NTLEAs. Hence, reducing the prevalence of PAD significantly improves public health and quality of life by reducing the disease burden on families, individuals, and society (Elfghi et al., 2021). Moreover, PAD is significantly associated with other chronic conditions, including diabetes, high blood pressure, ulcers, amputations, and gangrene (Lin et al., 2022; Matsushita et al., 2019; Mukherjee & Eagle, 2010; Serra et al., 2021). The complications advanced by PAD and NTLEA significantly increase the risk of mortality and morbidity in society.

PAD adversely affects productivity in society. Individuals diagnosed with PAD experience increased complications managing daily routine due to reduced mobility associated with PAD ischemia that includes pain during rest, gangrene, infections, and sores from lack of blood flow to the legs (Campia et al., 2019; Eid et al., 2021; Jelani et al., 2018; Paisley et al., 2022). Thus, by reducing the prevalence of PAD, individuals' and society's quality of life is improved. Moreover, given the association with various chronic conditions, management of PAD will lead to spillover positive health outcomes relating to the societal prevalence of chronic conditions such as diabetes, improving the outlook of healthcare outcomes (Conte et al., 2019; Creager et al., 2021; Minc et al., 2021; Parmenter et al., 2015). Therefore, the current study generated findings that may help reduce the occurrence of NTLEA among these societal factions. Disparities, especially in health outcomes, are significant diminishing factors for societal change and development. The current study's findings significantly discuss the risk factors for health disparities among BAs diagnosed with PAD (Eid et al., 2021; Matsushita et al., 2019).

Cogburn (2019) argued for the need for targeted interventions to reduce health inequalities since improving the general public's health may be insufficient in the change process of eliminating racial disparities in population health. Similarly, Agurs-Collins et al. (2019) argued that adopting multilevel health interventions to reduce disparities achievable through clearly identifying problem areas using methodological, data analytic assessment of challenges and designing uniquely effective interventions. In this regard, the current quantitative study on risk factors for PAD-oriented amputations among BAs provides uniquely targeted recommendations for tackling the problem of PAD disparities creating a disproportionate burden of disease among BAs. Curating unique intervention strategies targeting the PAD menace in Black communities will contribute to positive social change.

Discipline

While prior research has examined some NTLEA individual risk factors, the current study, through the use of SCT, went beyond by helping understand the magnitude of these risks among BAs and whether the absence or type of health insurance may modify the association between comorbidities and the occurrence of PAD-related amputation, specifically among BAs (Garcia et al., 2019; Minc et al., 2021). Studies have noted that BAs have a higher prevalence of PAD and related NTLEA than other racial and ethnic groups, attributed to the higher prevalence of risk factors, including high blood pressure and diabetes, among BAs. According to Tan et al. (2020), an estimated 25% of BAs between ages 65 and 74 are diagnosed with diabetes. Consequently, more than 40% of BAs are affected by high blood pressure, which develops earlier in the life trajectory of BAs, leading to more severe implications than in Whites. Moreover, Matsushita et al. (2019) depicted that BAs have a higher incidence rate of asymptomatic PAD, which puts the population at an increased risk of delayed care.

The limited access to quality healthcare due to disparities promulgated by racial discrimination and socioeconomic disadvantages among BAs may increase PAD-related NTLEA. According to Eid et al. (2021), the disproportionate prevalence of PAD among BAs and the limited access to management interventions contribute to increased amputation rates among Black American patients. For instance, Demsas et al. (2022) posited that healthcare providers are less likely to perform preventative vascular screenings and procedures among BAs and other minority groups. Moreover, revascularization for lower extremity arterial vascular diseases is recommended before considering amputation. Even so, BAs are four times more likely to receive NTLEA for severe PAD conditions than revascularization. Hackler et al. (2021) noted that BAs living with critical PAD-related limb ischemia are highly likely to receive amputations even under the treatment of highly specialized revascularization experts. These studies indicate that even after adjusting for the disparities in care access, BAs are still disproportionately targeted for NTLEA, with providers choosing amputations instead of revascularization.

Furthermore, PAD impacts around 21 million Americans, and approximately 11% of those diagnosed with PAD are expected to encounter complications that elevate their risk of amputation and premature mortality (Barnes et al., 2020; Bernatchez et al., 2021). The escalating incidence of NTLEAs, closely linked to severe PAD complications, constitutes an epidemic that diminishes an individual’s quality of life and imposes a substantial social and economic burden on communities (Creager et al., 2021). BA patients are at a significantly higher risk of PAD-related amputations, and the incidence is two times higher than in Whites and Hispanics due to severe PAD complications (Barnes et al., 2020; Garcia et al., 2019). While previous research has investigated the association between demographics (such as race, gender, and age), there is little information on the association of median household income, comorbidities (diabetes, kidney disease, CVD), and insurance accessibility and the effect modification between risk factors and health insurance status on the occurrence of NTLEA among BAs diagnosed with PAD (Hackler et al., 2021). The complex modification of the association between risk factors is ill-defined (Hackler et al., 2021). Identifying risk factors and understanding the effect modification between comorbidities (CVD, kidney disease, and diabetes mellitus) and

NTLEA among BAs diagnosed with PAD by health insurance status (private insurance, Medicaid, Medicare, self-pay) can potentially help improve outcomes, thereby reducing morbidity and premature death.

Summary and Conclusions

PAD is among the most prevalent CVDs, accounting for 31% of deaths globally (Lopez et al., 2022). A preliminary study by Mukherjee and Eagle (2010) indicated that approximately 8 million people died from PAD-related complications in the United States alone, noting that patients with PAD are six times more likely to experience cardiovascular causes of mortality compared to CVD patients without PAD. Yost (2023) posited that despite the 21st-century advancements in healthcare, compared to the preliminary study, the population has aged and become considerably highly diabetic, the two critical risk factors for PAD. Thus, research by Yost (2023) investigating the prevalence of PAD in the United States in 2020 found that compared to preliminary studies, the prevalence of PAD increased to 21 million and estimated a forecasted increase to 26 million. In this regard, PAD remained a severe healthcare concern for professionals worldwide, with an increased call to action for cost-effective strategies to address the modifiable risk factors in regions with an increased burden of PAD (Lin et al., 2022). However, even more alarming is the racial and ethnic disparity in PAD-related disease burden, especially for BAs in the United States.

According to Demsas et al. (2022), approximately 30% of PAD patients are BAs, with an increased disease burden experienced from age 60. As a result, BAs bear a higher burden of NTLEAs resulting from severe PAD, highlighting the need to evaluate PAD health inequities and provide recommendations for the clinical management of BA patients with PAD (Hackler et al., 2021). The knowledge generated from this study is anticipated to assist healthcare professionals in identifying at-risk populations. Consequently, healthcare professionals can apply the findings to reduce the occurrence of PAD-related amputations among BAs and the wider population and the associated mortality risks, improve individual quality of life, and reduce the financial burden and healthcare disparities.

It is not known to what extent specific demographics, comorbidities, access to health insurance, and the type of insurance influence the occurrence of PAD-related amputations in BAs and to what degree health insurance status may modify the association between comorbidities and NTLEA among BAs with PAD outcomes. That is the research problem that is addressed in this study. Hence, the proposed quantitative retrospective cross-sectional study seeks to explore the association between the independent variables, age, gender, median household income, comorbidities (CVD, kidney disease, diabetes mellitus), health insurance status (private insurance, Medicaid, Medicare, self-pay), and the occurrence of the dependent variable, PAD-related amputations in BAs, and whether health insurance modifies the association between comorbidities and NTLEA.

Section 2: Research Design and Data Collection

Introduction

BA patients are at a significantly higher risk of PAD-related amputations, and the incidence is two times higher than it is in Whites and Hispanics due to severe PAD complications (Barnes et al., 2020; Garcia et al., 2019). While previous research has investigated the association between demographics (such as race, gender, and age), there is little information on the association of median household income, comorbidities (diabetes, kidney disease, CVD), insurance accessibility, and the effect modification between risk factors and health insurance status on the occurrence of NTLEA among BAs diagnosed with PAD (Elfghi et al., 2021; Hackler et al., 2021). The purpose of this quantitative retrospective cross-sectional study was to explore the association between the independent variables, age, gender, median household income, comorbidities (CVD, kidney disease, diabetes mellitus), health insurance status (private insurance, Medicaid, Medicare, self-pay), and the occurrence of the dependent variable, PAD-related amputations in BAs, and whether health insurance modifies the association between comorbidities and NTLEA.

In Section 2, I present an extensive overview of the study methodology. The overview is categorized into several key methodological segments, including research design and rationale, population, sampling techniques, instrumentation and operationalization of variables, data analysis plan, threats to validity, and ethical procedures. The section concludes with an overall summary of the study methods and procedures.

Research Design and Rationale

This study applied a quantitative retrospective cross-sectional research design. A cross-sectional research design is a type of observational study approach that may appropriately measure the outcome and the exposures of the research participants at the same time (Spector, 2019). Cross-sectional studies are predominantly used to determine the pervasiveness of a problem (Wang & Cheng, 2020). These descriptions align with the purpose of the study, which was to explore the factors that influence the prevalence of PAD-related amputations in BA patients. The benefit of a cross-sectional design is that it facilitates the comparison of diverse variables at the same time (Wang & Cheng, 2020). Accordingly, a cross-sectional design was applied in this study to compare a set of independent variables and the dependent variable simultaneously. The independent variables included age, gender, median household income, comorbidities (CVD, kidney disease, diabetes mellitus), and health insurance status (private insurance, Medicaid, Medicare, self-pay), while the dependent variable was the occurrence of PAD-related amputations in BAs. Health insurance status was also used as a modifying variable of the relationship between comorbidities and NTLEA.

The cross-sectional design was retrospective because secondary data were used. According to Talari and Goyal (2020), in retrospective research, the targeted outcome had already happened when the study was started. A retrospective design enables the formulation of ideas regarding likely relationships and explores potential associations, even though causal statements normally should not be made because this is an observational design (Wojszel & Kasiukiewicz, 2019). In this study, a secondary data set from the NIS database was analyzed retrospectively to help determine the association between age, gender, median household income, comorbidities, health insurance status, and PAD-related amputations in BAs and whether it is a modification of the association between comorbidities and NTLEA by health insurance. A quantitative retrospective cross-sectional research design was used to carry out a multilevel observation of the risk factors demographics (i.e., median household income, gender, and age), comorbidities (CVD, kidney disease, and diabetes mellitus), health insurance access and type of health coverage, and the effect modification of the association between comorbidities (CVD, kidney disease, and diabetes mellitus) and NTLEA among BA diagnosed with PAD by health insurance status (private insurance, Medicaid, Medicare, self-pay).

Methodology

Secondary data from the 2020 NIS were obtained from the AHRQ and were used in this study. NIS, a component of the Healthcare Cost and Utilization Project (HCUP), is the most extensive publicly accessible all-payer inpatient healthcare catalog intended to produce U.S. national and regional approximations of inpatient utilization, outcome, quality, access, and cost (Meier et al., 2022). The purchased data were approved after I completed the HCUP data use agreement training, data use agreements, responsibility of data purchaser, and indemnification clause, statement of intended use, and sent an email to HCUP stating the purpose for using the NIS 2020 data set and attaching a copy of my Walden University transcript.

The NIS is sourced from 48 states and the District of Columbia, encompassing 98% of the U.S. population (Meier et al., 2022). The NIS constitutes an approximately

20% stratified sample of all discharges from U.S. community hospitals, with exclusions for long-term acute care and rehabilitation hospitals (Ezetendu et al., 2022). The systematic sampling methodology employed by the NIS mirrors simple random sampling, ensuring the sample is representative of the population across critical factors. These factors include hospital ownership, census category of the hospital, hospital teaching status, admission month of the hospital stay, diagnosis-associated group for the hospital stay, number of beds in the hospital, and urban-rural locality of the hospital (Onyeaka et al., 2019). NIS comprises data from over 7 million unweighted hospital stays annually and 35 million weighted hospitalizations countrywide (Meier et al., 2022). The NIS database has been found to correlate well with other discharge catalogs in the United States. It has been validated in different research studies to offer reliable approximations of admissions within the country. The specific target population from this secondary data included BAs diagnosed with PAD. The study sample included secondary data for all BAs diagnosed with PAD and included in the 2020 NIS.

Sampling and Sampling Procedure in Secondary Data Collection

The NIS adopts a disproportionate stratified sample approach for landline telephone samples and employs random sampling for cell phone samples. In disproportionate stratified sampling, the sample size from each stratum is not proportionate to its size in the overall population (Iliyasu & Etikan, 2021). NIS utilizes this method to ensure that even the smallest groups in the population have a sufficient sample for analysis, addressing the needs of various stakeholders in the study.

Sample Size and Sampling Procedure

The cross-sectional analysis involved extracting data points on these variables from the comprehensive NIS data set. The points were used to evaluate whether demographics (median household income, gender, and age), comorbidities (CVD, kidney disease, and diabetes mellitus), and health insurance access and type of health coverage influence modification of the association between comorbidities (CVD, kidney disease, and diabetes mellitus) and NTLEA among BAs diagnosed with PAD by health insurance status (private insurance, Medicaid, Medicare, self-pay). By employing disproportionate stratified sampling, stakeholders have the flexibility to evenly distribute the total sample size among subgroups or utilize varying proportions tailored to the unique requirements of distinct surveys (Elfghi et al., 2021). In the case of cell phone survey modules, households are randomly selected from blocks of phone numbers within a region. NIS further incorporates iterative proportional fitting or raking to correct demographic imbalances between the sampled participants and the broader population they represent (Meier et al., 2022). The 2009 NIS encompasses discharge data from 1,050 hospitals in 44 states, representing an approximately 20% stratified sample of U.S. community hospitals. The sampling frame for the 2020 NIS consists of a sample of hospitals that includes around 95% of all hospital discharges in the United States (Meier et al., 2022).

All possible participant data were used for analysis in the study. The NIS identifies hospitals using a stratified random selection approach to assure representation across many hospital characteristics, such as geography, size, teaching status, and ownership. This sampling strategy aims to produce a nationally representative sample. A priori sample size estimation was conducted using G*Power 3.1.9.7 to determine the required sample size for a logistic regression analysis. The computation was based on a two-tailed test with an odds ratio of 1.3, a null hypothesis probability $P(Y=1|X=1) = .2$, a significance level (α) of .05, and a power ($1-\beta$) of .95. To account for five predictors in the model, the R^2 for other predictors was set to .30, reflecting 30% of the variance explained by predictors other than the variable of interest. The predictor variable was assumed to follow a normal distribution with a mean (μ) of 0 and standard deviation (σ) of 1. The results indicated a critical z-value of 1.95996, with a required total sample size of 1,696 participants to achieve the desired power (see Appendix A).

In this study, the effect size from the binomial logistic regression analysis was used to assess the strength of the relationship between independent variables and the binary outcome variable. In logistic regression, the odds ratio (OR) is often used to measure effect size (Chu et al., 2021). The OR is the change in the probability of an event occurring for every one-unit change in the independent variable. The OR helps to understand how the likelihood of the result changes as the independent variable changes while other variables in the model are accounted for. An OR of 1 shows no effect, an OR more than 1 suggests a positive effect and an OR less than 1 indicates a negative effect. The magnitude of the OR and its confidence interval are used to estimate the effect size. A strong OR (far from 1) with a narrow confidence interval implies a significant effect, whereas a low OR with a wide confidence interval indicates a weak or uncertain effect. This information can help policymakers and practitioners identify possible risk or protective factors for the occurrence of PAD-related amputations in BAs and build targeted preventive and intervention plans. The alpha value (also known as the significance level) will be set at .05 (5%), indicating that if the proposed binary logistical regression analysis yields a *p*-value less than .05, the result is statistically significant. Secondary data owners also used this value; therefore, it is reasonable to expect this study to do the same.

Inclusion and Exclusion Criteria

Compiled annually by AHRQ since 1988, the NIS encompasses a substantial volume of inpatient discharges from U.S. community hospitals, irrespective of the payer, with each data point representing a distinct hospitalization (Ezetendu et al., 2022). Serving as a nationwide premier system for health-related telephone surveys, the NIS gathers state-specific data on the health-related risk behaviors of U.S. residents. The NIS also includes severity adjustment data elements such as APR-DRGs, APS-DRGs, disease staging, AHRQ comorbidity indicators, hospital structural characteristics, and the provision of outpatient services (Ezetendu et al., 2022). The NIS additionally provides information on patient demographics, administrative codes for primary and secondary diagnoses, procedures, survival to discharge, disposition, hospital charges, and length of stay (Meier et al., 2022). All non-institutionalized state residents age 18 and older are eligible for participation in NIS surveys.

Variable Description

The independent variables include age, gender, median household income, comorbidities (CVD, kidney disease, diabetes mellitus), and health insurance status (private insurance, Medicaid, Medicare, self-pay), while the dependent variable is the occurrence of PAD-related amputations in BAs. Health insurance status was also used as a modifying variable of the relationship between comorbidities and PAD-related NTLEA. The independent variables are a mixture of nominal, ratio, and interval-level variables. Conversely, the dependent variable is dichotomous or binary because it was measured as either the occurrence or non-occurrence of NTLEA among BAs diagnosed with PAD.

Data Analysis Plan

The most current version of IBM Statistical Package for Social Science (SPSS) was utilized to analyze the collected secondary data. The first step of analysis was to clean and organize the data. During this process, I checked for missing information and variables, inconsistencies, and outliers in the data. Proper editing of the data was done upon discovery of missing information, inconsistencies, and outliers. Editing procedures were repeated to ensure that all missing variables and inaccuracies were adjusted. The cleaned data were analyzed using both descriptive and inferential methods. Descriptive statistics such as means, percentages, and frequencies were used to characterize the sample by demographic factors (age, gender, median household income), comorbidities (CVD, kidney disease, diabetes mellitus), health insurance status (private insurance, Medicaid, Medicare, self-pay), and the occurrence of PAD-related amputations in BAs.

Descriptive statistics, such as frequencies and percentages, were used to show the independent categorical variables, allowing a trend to emerge from the data and showing how the individual observations are distributed. The central tendency was used for continuous independent variables to determine where the majority of values in a distribution fall: normally distributed data by means and standard deviation (*SD*) and skewed distributions by median and inter-quartile range (IQR).

Binomial logistical regression analysis was used for inferential analysis involving the dependent and independent variables to determine the effects of age, gender, median household income, comorbidities (CVD, kidney disease, diabetes mellitus), and health insurance status (private insurance, Medicaid, Medicare, self-pay) on the occurrence of PAD-related amputations in BAs. However, to use the binomial logistical regression analysis correctly and produce valid results, the data must have always met specific assumptions. Although logistic regression analysis is very robust, it is common practice to determine the degree of divergence from these assumptions to ensure the validity of the results.

Assumptions

To use logistic regression analysis, which is a parametric test, six assumptions must be met (Statistics.laerd.com, 2018):

Assumption 1

Assumption 1 states that the dependent variable should be separated into two unrelated groups (a dichotomous variable) (Statistics.laerd.com, 2018). The study's dependent variable is dichotomous or binary because it is measured as the occurrence or non-occurrence of NTLEA among BAs with PAD.

Assumption 2

The second assumption is that two or more independent variables are present, which can be continuous or categorical (Statistics.laerd.com, 2018). The independent variables are age, gender, median household income, comorbidities (CVD, kidney disease, or diabetes mellitus), and health insurance status (private insurance, Medicaid, Medicare, or self-pay). Health insurance status will be used for modifying the relationship between comorbidities and PAD-related NTLEA. The independent variables consist of nominal, ratio, and interval-level variables.

Assumption 3

Assumption 3 states that observations should be independent. In other words, each observation in the data collection should be unique from the others. This means that one observation's result should not influence another's outcome. For example, in the secondary data, I analyzed data from the NIS, and only data relevant to the study were extracted; each observation represented data from individual patients, and all patients were independent of one another and had no other data-related relationships. Furthermore, multiple hospitals that were unrelated to one another participated in data collection.

Assumption 4

The fourth assumption is that any continuous independent variables must have a linear relationship with the logit transformation of the dependent variable (Statistics.laerd.com, 2018). A scatter plot will evaluate this assumption, which will be visually examined to determine linearity. When this assumption is broken, one solution is to convert the target variable to a normal variable. This also has the benefit of normalizing errors. The log and square root transformations are the most popular. The scatter plot should not show a U-shaped pattern for the linear relationship.

Assumption 5

According to Statistics.laerd.com (2018), this assumption means that the data must not exhibit multicollinearity, which occurs when two or more independent variables have a high degree of correlation with one another, implying that the two independent variables are unrelated. It may cause problems with coefficient estimation and interpretation. The variance inflation factor (VIF) was employed in the study to assess multicollinearity. According to the VIF, multicollinearity increases the variance of the estimated regression coefficient for an independent variable. A score of 10 or more indicates significant multicollinearity between the variables and that the assumption is not met, whereas a score of 1 indicates no multicollinearity.

Assumption 6

The data set should have no significant outliers, high leverage points, or major influencing points that represent observations that are out of the ordinary (Statistics.laerd.com, 2018). These can have a considerable negative impact on the binomial logistic regression equation, which predicts the value of the dependent variable based on the independent variables (Statistics.laerd.com, 2018). The assumption can be tested using box plots. Cook's distance was calculated in addition to the visual inspection of box plots to determine whether outliers have an undue influence on the analysis. In this case, readings of 1.0 or above are problematic, and additional diagnostics were performed to determine whether an undue influence occurred (Gress et al., 2018).

The inferential analysis was conducted using logistic regression, OR calculation, multivariable regression, and stratified analysis. A fundamental syntax was executed to present the ORs and their corresponding 95% confidence intervals for each predictor variable in the model. This preliminary step precedes exploring the relationship between independent and dependent variables through logistic regression. The recommended technique for logistic regression is to run individual variables in bivariate logistic models (just for exposure and outcome). Significant variables were noted so that they could be included in the final multivariate model. Confounding factors are those that produce a 10% or greater change in the observed relationship, are linked with the outcome, and are connected with exposure. The final model incorporated all statistically significant variables. If a significant variable were to become insignificant in the final model, the process would be repeated without it to determine the model's stability.

Logistic regression and OR were used to evaluate hypotheses for RQ1, RQ2, and RQ3. Also, assuming that there was an association with increasing age, median household income, and gender, I treated them as confounders and controlled for these covariates in RQ2, RQ3, and RQ4. The confounders in the study were controlled and measured with logistic regression that will give an adjusted OR.

For RQ4, multivariable logistical regression and OR were used alongside stratified analysis to determine whether there is a modification of the association between comorbidities (CVD, kidney disease, and diabetes mellitus) and NTLEA among BAs diagnosed with PAD by health insurance status (private insurance, Medicaid, Medicare, self-pay). The stratified analysis facilitated the categorization of data into strata by health insurance status (private insurance, Medicaid, Medicare, and self-pay). Multivariable regression were used to explore the effect modification (risk effect) of health insurance status (private insurance, Medicaid, Medicare, and self-pay) that differentially (positively and negatively) modifies the observed effect of risk factors (CVD, kidney disease, and diabetes mellitus) and NTLEA among BAs diagnosed with PAD. The systematic stratified analysis approach involves the following steps: (a) conduct stratified analysis by the third variable, health insurance status (private insurance, Medicaid, Medicare, and self-pay); and (b) homogeneity of ORs tested to determine whether these measures of association are significant. Significance indicates a significant effect modification.

Threats to Validity

The merits of a quantitative research study and its statistical outcomes rely on its internal and external validity (Sürücü & Maslakçi, 2020). Each kind of validity has related threats, some of which are more common in cross-sectional studies. Internal and external validity and their related threats are discussed comprehensively in this segment.

Internal Validity

Internal validity refers to the level at which systematic error is reduced in a research study to facilitate a more accurate evaluation of relationships between study variables (Sürücü & Maslakçi, 2020). It is also the level at which it is assumed that the independent variable (s) measure of association is causally related to the response variable (Sürücü & Maslakçi, 2020). Threats to internal validity comprise all sources of systematic error or bias. These include selection bias, information bias, confounding, and causal ambiguity (Ampatzoglou et al., 2019). These threats are unlikely to impact the proposed study because the study will utilize secondary data. Issues likely to influence the internal validity of the proposed study comprise missing variables and missing data.

External Validity

External validity pertains to whether the research outcomes are generalizable to the overall population (Ampatzoglou et al., 2019). The study would have external validity if the outcomes in the sample of BAs diagnosed with PAD in 2020 NIS were easily associated with the results of all BAs diagnosed with PAD across the United States. To overcome threats to external validity, secondary data for all BAs diagnosed with PAD included in the 2020 NIS were explored. The sample size was sufficiently large to ensure the generalizability of findings, given that the NIS includes data from over 7 million unweighted hospital stays annually and 35 million weighted hospitalizations nationwide. The utilization of a large sample would also guarantee adequate statistical power, ensuring the research outcomes are broadly applicable.

Ethical Procedures

Fundamental ethical procedures were followed while conducting the study. The first ethical procedure was to seek Institutional Review Board approval to use the suggested secondary data and conduct the study. NIS is freely available in HCUP, implying that no permission would be needed to access and use the data. Patient confidentiality was maintained by removing personally identifiable information from the dataset. The collected data were stored safely with a complex passcode and were utilized only for the study. These data will be stored for at least 5 years to facilitate future analysis and will only be accessed under restricted situations. The physical data will be securely disposed of upon completion, and digital data will be irretrievably deleted from all storage media.

Summary

A quantitative, retrospective, cross-sectional research design was used to conduct a multilevel observation of the risk factors, including demographic variables, comorbidities (CVD, kidney disease, and diabetes mellitus), health insurance access and coverage type, and the effect modification of comorbidities on NTLEA among BAs diagnosed with PAD, stratified by health insurance status (private insurance, Medicaid, Medicare, self-pay). Secondary data from the 2020 NIS were used in this study. The collected data were analyzed using both descriptive and inferential methods. Descriptive statistics such as means, percentages, and frequencies were applied to characterize the sample by demographic factors, comorbidities, health insurance status, and the occurrence of PAD-related amputations in BAs. The inferential analysis methods included logistic regression, OR, multivariable regression, and stratified analysis. Logistic regression was appropriate for this study because the dependent variable is dichotomous. The dependent variable was measured as either the occurrence or non-occurrence of NTLEA among BAs diagnosed with PAD. Multivariable regression was used to explore the effect of modification of health insurance status in the association between comorbidities and NTLEA among BAs diagnosed with PAD. These analyses were performed in IBM SPSS Version 26. Section 3 presents the study results and findings.

Section 3: Presentation of the Results and Findings

Introduction

This quantitative retrospective cross-sectional study sought to investigate the relationship between independent variables such as age, gender, median household income, comorbidities (CVD, kidney disease, diabetes mellitus), health insurance status (private insurance, Medicaid, Medicare, self-pay), and the occurrence of the dependent variable: PAD-related amputations in Black or AA individuals. The study also intended to evaluate whether health insurance modified the relationship between comorbidities and PAD-related amputations. The current study was necessary because it is unknown to what extent specific demographics, comorbidities, access to health insurance, and the type of insurance influence the occurrence of PAD-related amputations in BAs or to what extent health insurance status modifies the association between comorbidities and NTLEA among BAs with PAD.

The following research questions and null hypotheses guided the study.

RQ1: Is there an association between demographics, including median household income, gender, and age, and the occurrence of NTLEA among BAs diagnosed with PAD?

$H_0$1: There is no association between median household income, gender, and age and the occurrence of NTLEA among BAs diagnosed with PAD.

H_A1: There is an association between median household income, gender, and age and the occurrence of NTLEA among BAs diagnosed with PAD.

RQ2: Is there an association between health insurance status (private insurance, Medicaid, Medicare, self-pay) and the occurrence of NTLEA among BAs diagnosed with PAD while controlling for age, median household income, and gender (confounders)?

$H_0$2: When age, median household income, and gender are controlled, there is no association between health insurance status (private insurance, Medicaid, Medicare, self-pay) and the occurrence of NTLEA among BAs diagnosed with PAD.

H_A2: When age, median household income, and gender are controlled, there is an association between health insurance status (private insurance, Medicaid, Medicare, self-pay) and the occurrence of NTLEA among BAs diagnosed with PAD.

RQ3: Is there an association between comorbidities (namely CVD, kidney disease, and diabetes mellitus) and the occurrence of NTLEA among BAs diagnosed with PAD while controlling for age, median household income, and gender (confounders)?

$H_0$3: When age, median household income, and gender are controlled, there is no association between comorbidities (namely CVD, kidney disease, and diabetes mellitus) and the occurrence of NTLEA among BAs diagnosed with PAD.

H_A3: When age, median household income, and gender are controlled, there is an association between comorbidities (namely CVD, kidney disease, and diabetes mellitus) and the occurrence of NTLEA among BAs diagnosed with PAD.

RQ4: Is there an effect modification of the association between comorbidities (CVD, kidney disease, and diabetes mellitus) and NTLEA among BAs diagnosed with

PAD by health insurance status (private insurance, Medicaid, Medicare, self-pay) while controlling for age, median household income, and gender (confounders)?

$H_0$4: When age, median household income, and gender are controlled, there is no effect modification of the association between comorbidities (CVD, kidney disease, and diabetes mellitus) and NTLEA among BAs diagnosed with PAD by health insurance status (private insurance, Medicaid, Medicare, self-pay).

H_A4: When age, median household income, and gender are controlled, there is an effect modification of the association between comorbidities (CVD, kidney disease, and diabetes mellitus) and NTLEA among BAs diagnosed with PAD by health insurance status (private insurance, Medicaid, Medicare, self-pay).

This section incorporates the study's results and findings. The section covers the study's findings, starting with a summary of the data-gathering process and a description of the participants' demographics. Then, I present descriptive statistics for the study's primary variables, followed by a deeper examination of statistical assumptions using binomial logistic regression. The structure of this section is organized into four primary subsections: (a) an introduction, which sets the setting for the results and findings; (b) data collection, which describes the methods utilized to collect data; (c) the results, which presents the outcomes of the data analysis; and (d) a summary, which provides a brief overview of the findings and the resulting implications.

Data Collection

Secondary data from the 2020 NIS were obtained from the AHRQ and used in this research. NIS, a component of the HCUP, is the most comprehensive publicly accessible all-payer inpatient healthcare catalog in the United States to produce national and regional estimates of inpatient utilization, outcome, quality, access, and cost. The purchased data were approved after I completed the HCUP data use agreement training, data use agreements, responsibility of data purchaser, and indemnification clause, statement of intended use, and sent an email to HCUP stating my intention to use the NIS 2020 data set and attaching a copy of my Walden University transcript.

The NIS data are compiled from 48 states and the District of Columbia, representing 98% of the U.S. population. They use a stratified sample of about 20% of all discharges from U.S. community hospitals, with the exception of long-term acute care and rehabilitation facilities. The NIS uses systematic sampling methods, which are similar to basic random sampling, to ensure the sample is representative of the population across essential factors.

Prior to analysis, the data underwent preliminary cleaning procedures to ensure accuracy and reliability. The initial size of the NIS 2020 data was 6,246,588 valid records, and of these, Black or AA individuals represented 15.8% of the sample (*n* = 988,205). Of these, 9,731 BAs (1.0%) had PAD; these were the individuals included in the sample for analysis. Of those with PAD, about 22.0% (*n* = 2,140) had lower extremity amputations.

Table 1 summarizes the demographic and hospitalization record characteristics of the eligible BAs in the research study. The research study included 9,731 individuals, with women accounting for 52.9% (*n* = 5,144) and men accounting for 47.1% (*n* = 4,587). The average age at admission was 66.1 years (*SD* = 12.5). In terms of the primary expected payer, the majority of individuals had Medicare coverage (66.4%, *n* = 6,447), followed by Medicaid (15.3%, *n* = 1,489) and private insurance, including HMOs (12.8%, *n* = 1,241). Most participants (54.0%, *n* = 5,166) had a median household income ranging from $1 to $49,999. The median length of stay in the hospital was 6.0 days (IQR 3-11). Patient location varied, with the majority of participants residing within central counties in metro counties with populations greater than 1 million (43.1%, *n* = 4,169). The majority of admissions were nonelective (79.5%, *n* = 7,724), with an average of 20.0 diagnoses per patient reported upon admission (*SD* = 7.1). Most participants (89.7%, *n* = 8,693) were not transferred from another facility, with 6.1% (*n* = 589) having been transferred from a different acute care hospital and 4.3% (*n* = 412) transferring from another type of health facility.

Table 1

Demographic and Hospitalization Characteristics

	Total	NTLEA		*p*
		No	Yes	
Sex				< .001
Male	5,144(52.9)	3,803 (50.1)	1,341 (62.7)	
Female	4,587 (47.1)	3,788 (49.9)	799 (37.3)	
Age at admission in years, M[SD]	66.1 [12.5]	66.3 [12.7]	65.5 [11.8]	.006
Primary expected payer				.827
Medicare	6,447 (66.4)	5,043 (66.6)	1,404 (65.8)	
Medicaid	1,489 (15.3)	1,155 (15.2)	334 (15.6)	
Private, including HMO	1,241 (12.8)	969 (12.8)	272 (12.7)	
Self-pay	269 (2.8)	209 (2.8)	60 (2.8)	
Other	263 (2.7)	198 (2.6)	65 (3.0)	
Median household income				.595
$1–$49,999	5,166 (54.0)	4,008 (53.7)	1,158 (54.9)	
$5,000–$64,999	2,188 (22.9)	1,706 (22.9)	482 (22.9)	
$65,000–85,999	1,362 (14.2)	1,080 (14.5)	282 (13.4)	
$86,000 or more	857 (9.0)	671 (9.0)	186 (8.8)	
Length of stay in days, Mdn [IQR]	6 [3-11]	5 [3-9]	10 [7-17]	< .001
Patient location				< .001
Central counties of metro areas of ≥ 1 million population	4,169 (43.1)	3,310 (43.9)	859 (40.3)	
Fringe counties of metro areas of ≥ 1 million population	1,991 (20.6)	1,558 (20.7)	433 (20.3)	
Counties in metro areas of 25,000–999,999 population	1,775 (18.3)	1,402 (18.6)	373 (17.5)	
Counties in metro areas of 5,000–249,999 population	713 (7.4)	548 (7.3)	165 (7.7)	
Micropolitan counties	588 (6.1)	432 (5.7)	156 (7.3)	
Not metropolitan or micropolitan counties	438 (4.5)	294 (3.9)	144 (6.8)	
Elective versus non-elective admission				.975
Non-elective	7,724 (79.5)	6,024 (79.5)	1,700 (79.5)	
Elective	1,993 (20.5)	1,555 (20.5)	438 (20.5)	
Number of diagnoses, M [SD]	20.0[7.1]	19.7 [7.1]	21.1 [7.0]	< .001
Transfer in indicator				.192
Not a transfer	8,693 (89.7)	6,804 (90.0)	1,889 (88.7)	
Transferred in from a different acute care hospital	589 (6.1)	443 (5.9)	146 (6.9)	
Transferred in from another type of health facility	412 (4.3)	317 (4.2)	95 (4.5)	

Note. *M* = Mean; *SD* = standard deviation; Mdn = median; IQR = inter-quartile range; *p* = significance test for proportions (Pearson chi square), means (ANOVA), and median (Mann-Whitney U). Missing data: Handfuls of variables had missing data and were omitted from the analysis using casewise deletion.

The results presented in Table 1 also compare demographic and hospitalization characteristics between individuals who did and did not undergo NTLEA. A significant difference was found between men and women, with a higher proportion of men undergoing NTLEA (62.7%) compared to women (37.3%), $p < .001$. The mean age at admission was also significantly different between groups, with individuals who underwent NTLEA being slightly younger (*M* = 65.5, *SD* = 11.8) than those who did not (*M* = 66.3, *SD* = 12.7), *p* = .006.

The primary expected payer did not significantly differ between the NTLEA and non-NTLEA groups, *p* = .827. Similarly, median household income was not significantly associated with NTLEA, *p* = .595. However, the length of stay was significantly longer for individuals who underwent NTLEA (*Mdn* = 10 days, *IQR* = 7-17) compared to those who did not (*Mdn* = 5 days, *IQR* = 3-9), *p* < .001. The length of stay variable captured the total count of diagnoses recorded for a single inpatient stay. Patient location was significantly associated with NTLEA, *p* < .001, with a higher proportion of NTLEA patients residing in non-metropolitan or micropolitan counties. There was no significant difference between the groups regarding elective versus non-elective admission, *p* = .975. Lastly, the number of diagnoses was significantly higher in the NTLEA group (*M* = 21.1, *SD* = 7.0) compared to the non-NTLEA group (*M* = 19.7, *SD* = 7.1), *p* < .001. There was no significant association between transfer status and NTLEA, *p* = .192.

Results

The goal of this quantitative retrospective cross-sectional study was to investigate the relationship between the independent variables age, gender, median household income, comorbidities (CVD, kidney disease, diabetes mellitus), health insurance status (private insurance, Medicaid, Medicare, self-pay), and the occurrence of the dependent variable, PAD-related amputations in BAs, as well as whether health insurance modifies the relationship between comorbidities and NTLEA. The independent variables were age, gender, median household income, comorbidities (CVD, kidney disease, diabetes mellitus), and health insurance status (private insurance, Medicaid, Medicare, self-pay), while the dependent variable was the occurrence of PAD-related amputations in BAs. Health insurance status was also used as a modifying variable of the relationship between comorbidities and PAD-related NTLEA. The independent variables consisted of nominal, ratio, and interval-level variables. On the other hand, the dependent variable was dichotomous or binary, meaning it was quantified as the presence or absence of NTLEA among BAs with PAD.

This subsection aims to present the results of the secondary data analysis. However, before the findings were presented, assumption analysis was carried out to demonstrate the validity of the results obtained using logistic regression analysis. A descriptive analysis of the comorbidities and dependent variables will be presented before the results of the logistic regression analysis findings, organized by research questions and/or hypotheses, are summarized.

Assumption Analysis

Binomial logistic regression analysis was used to determine whether there was a statistically significant relationship between age, gender, median household income, comorbidities (CVD, kidney disease, diabetes mellitus), health insurance status (private insurance, Medicaid, Medicare, self-pay), and the occurrence of the dependent variable: PAD-related amputations in Black or AA. However, some assumptions must always be followed to use binomial logistic regression analysis appropriately and obtain valid results. Even though binomial logistic regression analysis is highly robust, assessing the quality of the results by determining the degree of divergence from these assumptions is often recommended. Although six assumptions were put forward in Section 2, I presented the statistical assumption findings for three of them. The other three assumptions (formats of dependent and independent variables, and the independence of observations) were mostly based on the study design.

Linearity in the Logit

Any continuous independent variables are assumed to have a linear relationship with the dependent variable's logit transformation (Statistics.laerd.com, 2018). The study's only continuous variable was the participants' ages. This assumption was evaluated by utilizing the Box-Tidwell test to examine the assumption of linearity, specifically if the relationship between the continuous independent variable (age) and the log odds of the dependent variable (presence or absence of PAD) was linear. I accomplished this by multiplying the continuous independent variable (age) with its natural logarithm to create an interaction term. Next, I ran the logistic regression model, containing the original continuous variable, its interaction term, and the additional independent variables (median household income and gender). The model was tested for the coefficient of the interaction term for the continuous variable (see Table 2). If the coefficient deviates significantly from 0, it indicates that the relationship between the variable and log odds is not linear. In my study, the interaction term was not statistically significant (p =.697), showing that the linearity assumption was not violated.

Avoidance of Multicollinearity

According to Statistics.laerd.com (2018), this assumption requires that the data do not display multicollinearity, which occurs when two or more independent variables have a high degree of correlation with one another, meaning that the two independent variables should be unrelated. If the independent variables are colinear, coefficient estimation and interpretation may be compromised, affecting the interpretation of the results. The VIF was used in the study to determine multicollinearity for continuous variables and the chi-square test for categorical variables.

Table 2

Variables in the Equation for the Box-Tidwell Linearity Test

	B	SE	Wald	p
Age	.174	.581	.090	.765
Age * natural log age	-.038	.097	.152	.697
Natural log age	.934	5.228	.032	.858
Median household income				
$1–$49,999		Reference		
$50,000–$64,999	-.009	.062	.022	.883
$65,000–85,999	-.079	.075	1.109	.292
$86,000 or more	-.026	.090	.084	.772
Sex				
Male		Reference		
Female	-.495	.051	94.066	< .001
Constant	-5.947	10.328	.331	.565

Note. *B* = unstandardized coefficient; *SE* = standard error; Wald = Wald statistics; *p* = significance test at .05 level

The VIF indicates that multicollinearity increases the variance of the estimated regression coefficient for an independent variable. A score of 10 or above indicates strong multicollinearity between the variables and that the assumption is not met, while a score of 1 indicates no multicollinearity (Vatcheva et al., 2016). The only continuous independent variable in the study with an acceptable VIF value of 1.113 was age at enrollment, indicating that this assumption was not violated.

In studies involving categorical variables, Pearson's chi-square test is a commonly used statistical method to evaluate the association between two categorical variables. Although chi-square tests are typically used to assess independence between variables, they can also serve as a diagnostic tool to detect potential multicollinearity in data sets (Shatz, 2024). By examining the strength of associations between categorical variables, chi-square tests can help identify highly correlated variables, which might indicate multicollinearity. The chi-square test results showed strong relationships between numerous pairs of categorical variables, implying probable multicollinearity among them (see **Error! Reference source not found.**). Specifically, there were significant connections between the primary expected payer and almost every other variable, implying that it may be a crucial component determining multicollinearity in the data set.

Table 3

Pearson Chi-Square Tests

		1	2	3	4	5	6
1	Indicator of sex						
2	Median household income national	.352					
3	Cardiovascular disease	< .001	.454				
4	Kidney disease	.618	< .001	< .001			
5	Diabetes mellitus	.498	.341	.520	.704		
6	Primary expected payer	< .001	< .001	< .001	< .001	.851	

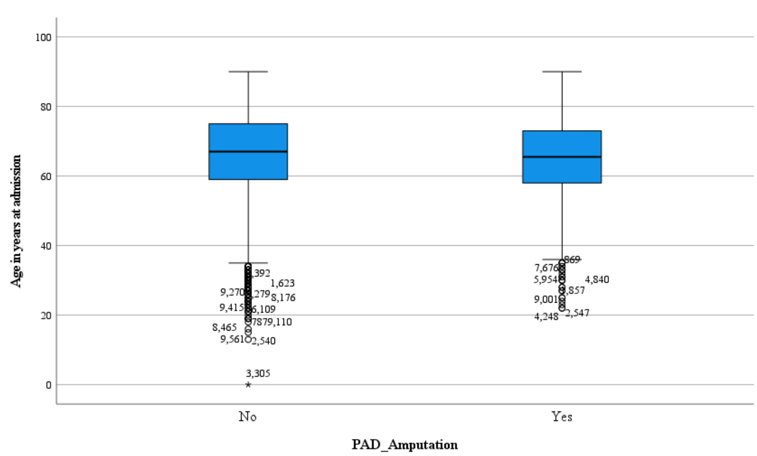
Note. The numbers in the column headings (1-6) represent the variables stated in Columns 1 and 2.

No Significant Outliers

The data set should not contain any significant outliers, high leverage points, or major influencing points that indicate unusual observations (Statistics.laerd.com, 2018). These can have a substantial adverse effect on the binomial logistic regression equation, which predicts the value of the dependent variable using the independent variables (Statistics.laerd.com, 2018). The assumption was visually tested with box plots, and then Cook's distance was used to check the impact of the outliers on the analyses (see figure 1). Some outliers were noted in the data. The Cook's distance was calculated in addition to the visual inspection of box plots to determine whether outliers had an undue influence on the analysis. Cook's distance readings of 1.0 or above are problematic, and those individual records should be dropped from the analysis (Gress et al., 2018). In this study, however, the Cook's distance values ranged from .000 to .088, implying that despite the presence of outliers, the analysis had no impact. The assumption was, therefore, not violated.

Figure 1

Box Plot Showing Distribution of Ages Among With and Without PAD



Research Question Findings

Research Question 1

The first question was to investigate whether there was an association between demographics, including median household income, gender, and age, and the occurrence of NTLEA among BAs diagnosed with PAD. A binomial logistic regression analysis was conducted to examine the association between demographics and the occurrence of NTLEA among individuals diagnosed with PAD (See Table 4). Both univariate (unadjusted) and multivariate (adjusted) analyses were conducted.

Results from the univariate analysis revealed that age at admission was significantly associated with NTLEA (OR = .995, 95% CI [.991, .999], *p* = .006), indicating that for every one-year increase in age, the odds of NTLEA decreased by approximately .5%. However, this effect became less pronounced and statistically non-significant (OR = .996, 95% CI: .992-1.000, *p* = .065) in the multivariate analysis, suggesting other variables might play a stronger role. Initially, age appeared to have a modest effect on NTLEA, with each additional year of age slightly decreasing the odds of NTLEA. However, this effect diminished and became statistically non-significant when other variables were included in the multivariate model. This shift may be due to confounding variables that overshadow the effect of age, such as socio-economic factors (household income and sex), which, when controlled for, revealed that age’s contribution to NTLEA was less pronounced. These results suggest that while age alone might have a weak association with NTLEA, other factors play a more substantial role in predicting NTLEA.

In univariate or multivariate analyses, income categories showed no statistically significant association with NTLEA. Sex, on the other hand, emerged as a significant predictor in both analyses. Unlike males, females had a substantially lower chance of experiencing NTLEA (OR = .598, 95% CI: .542-.660, *p* < .001 in both univariate and multivariate models).

Table 4

Association Between Demographics and the Occurrence of Nontraumatic Lower Extremity Amputation Among Black Americans Diagnosed With PAD

	Univariate 95% CI				Multivariate 95% CI			
	OR	Lower	Upper	p	OR	Lower	Upper	p
Age in years at admission	.995	.991	.999	.006	.996	.992	1.000	.065
Median household income								
$1–$49,999	Reference				Reference			
$50,000–$64,999	.978	.867	1.103	.716	.988	.875	1.115	.847
$65,000–85,999	.904	.781	1.046	.176	.911	.787	1.056	.217
$86,000 or more	.959	.805	1.143	.643	.961	.806	1.147	.662
Sex								
Male	Reference				Reference			
Female	.598	.542	.660	.000	.598	.541	.660	<.001

Note. OR = odds ratio; CI = confidence interval; *p* = significance test at .05 level (2-sided)

Research Question 2

The next question was if there was an association between health insurance status (private insurance, Medicaid, Medicare, self-pay) and the prevalence of NTLEA among BAs diagnosed with PAD after controlling for age, median household income, and gender (confounders). A logistic regression analysis was conducted to investigate the association between health insurance status and the prevalence of NTLEA among individuals diagnosed with PAD, controlling for age, median household income, and gender (see Table

Research Question 3

The third question to be addressed was if there was an association between comorbidities (namely CVD, kidney disease, and diabetes mellitus) and the occurrence of NTLEA among BAs diagnosed with PAD while controlling for age, median household income and gender (confounders). A logistic regression analysis was performed to explore the association between comorbidities and the occurrence of NTLEA among individuals diagnosed with PAD while controlling for age, median household income, and gender (see Table 6).

In the univariate analysis, several medical conditions were examined alongside demographic factors. Individuals with CVD had significantly lower odds of NTLEA compared to those without (OR = .804, 95% CI [.668, .968], p = .021). This association remained significant in the multivariate analysis (OR = .815, 95% CI [.671, .990], p = .039). Participants with kidney disease exhibited significantly higher odds of NTLEA than those without (OR = 1.175, 95% CI [1.065, 1.297], p = .001). This association persisted in the multivariate analysis (OR = 1.191, 95% CI [1.076, 1.318], p = .001). Individuals with diabetes mellitus had substantially higher odds of NTLEA than those without (OR = 7.106, 95% CI [1.301, 38.821], p = .024). This strong association remained significant even after adjusting for other variables in the multivariate analysis (OR = 6.730, 95% CI [1.207, 37.522], p = .030).

Table 5

Association Between Health Insurance Status and The Prevalence of NTLEA Among Black Americans Diagnosed With PAD

	Univariate				Multivariate			
		95% CI				95% CI		
	OR	Lower	Upper	*p*	OR	Lower	Upper	*p*
Primary expected payer								
Self-pay		Reference				Reference		
Medicare	.970	.723	1.300	.837	1.084	.797	1.472	.608
Medicaid	1.007	.737	1.376	.964	1.041	.757	1.432	.804
Private	.978	.712	1.342	.889	1.028	.743	1.424	.866
Other	1.144	.766	1.708	.512	1.102	.732	1.660	.643
Age	.995	.991	.999	.006	.996	.991	1.000	.043
Median household income								
$1–$49,999		Reference				Reference		
$50,000–$64,999	.978	.867	1.103	.716	.993	.879	1.121	.906
$65,000–85,999	.904	.781	1.046	.176	.912	.787	1.057	.222
$86,000 or more	.959	.805	1.143	.643	.967	.810	1.154	.708
Sex								
Male		Reference				Reference		
Female	.598	.542	.660	<.001	.597	.540	.660	<.001

Note. OR = odds ratio; CI = confidence interval; *p* = significance test at .05 level (2-sided)

Table 6

Association Between Comorbidities and the Occurrence of NTLEA Among Black Americans Diagnosed With PAD

5).

The logistic regression analysis examined the relationship between demographics and the incidence of NTLEA among individuals diagnosed with PAD. In the univariate analysis, primary expected payer status showed no significant association with NTLEA as compared to the reference category of self-pay, with Medicare (OR = .970, 95% CI [.723, 1.300], *p* = .837), Medicaid (OR = 1.007, 95% CI [.737, 1.376], *p* = .976), Private insurance (OR = .978, 95% CI [.712, 1.342], p = .889), and other payment methods (OR = 1.144, 95% CI [.766, 1.708], p = .512) all yielding non-significant results. Similarly, in the multivariate analysis, none of these payer categories exhibited statistically significant associations with NTLEA compared to self-pay, maintaining non-significance across the board. Age at admission remained significantly associated with NTLEA in both univariate (OR = .995, 95% CI [.991, .999], p = .006) and multivariate analyses (OR = .996, 95% CI [.991, 1.000], p = .043), indicating a protective effect with increasing age. The mean age at admission was significantly different between groups, with individuals who underwent NTLEA being slightly younger (M = 65.5, SD = 11.8) than those who did not (M = 66.3, SD = 12.7). Similarly, sex was significantly associated with NTLEA, with females demonstrating lower odds compared to males in both univariate (OR = .598, 95% CI [.542, .660], $p < .001$) and multivariate analyses (OR = .597, 95% CI [.540, .660], $p < .001$), indicating a consistent protective effect. Household income did not exhibit significant associations with NTLEA across all income categories in univariate or multivariate analyses. These results underscore the independent associations of age and sex with NTLEA among PAD patients. At the same time, primary expected payer status and household income did not demonstrate significant independent associations in this analysis.

Research Question 3

The third question to be addressed was if there was an association between comorbidities (namely CVD, kidney disease, and diabetes mellitus) and the occurrence of NTLEA among BAs diagnosed with PAD while controlling for age, median household income and gender (confounders). A logistic regression analysis was performed to explore the association between comorbidities and the occurrence of NTLEA among individuals diagnosed with PAD while controlling for age, median household income, and gender (see Table 6).

In the univariate analysis, several medical conditions were examined alongside demographic factors. Individuals with CVD had significantly lower odds of NTLEA compared to those without (OR = .804, 95% CI [.668, .968], $p = .021$). This association remained significant in the multivariate analysis (OR = .815, 95% CI [.671, .990], $p = .039$). Participants with kidney disease exhibited significantly higher odds of NTLEA than those without (OR = 1.175, 95% CI [1.065, 1.297], $p = .001$). This association persisted in the multivariate analysis (OR = 1.191, 95% CI [1.076, 1.318], $p = .001$). Individuals with diabetes mellitus had substantially higher odds of NTLEA than those without (OR = 7.106, 95% CI [1.301, 38.821], $p = .024$). This strong association remained significant even after adjusting for other variables in the multivariate analysis (OR = 6.730, 95% CI [1.207, 37.522], $p = .030$).

Table 5

Association Between Health Insurance Status and The Prevalence of NTLEA Among Black Americans Diagnosed With PAD

	Univariate				Multivariate			
		95% CI				95% CI		
	OR	Lower	Upper	*p*	OR	Lower	Upper	*p*
Primary expected payer								
Self-pay	Reference				Reference			
Medicare	.970	.723	1.300	.837	1.084	.797	1.472	.608
Medicaid	1.007	.737	1.376	.964	1.041	.757	1.432	.804
Private	.978	.712	1.342	.889	1.028	.743	1.424	.866
Other	1.144	.766	1.708	.512	1.102	.732	1.660	.643

	OR	Lower	Upper	p	OR	Lower	Upper	p
Age	.995	.991	.999	.006	.996	.991	1.000	.043
Median household income								
$1–$49,999		Reference				Reference		
$50,000–$64,999	.978	.867	1.103	.716	.993	.879	1.121	.906
$65,000–85,999	.904	.781	1.046	.176	.912	.787	1.057	.222
$86,000 or more	.959	.805	1.143	.643	.967	.810	1.154	.708
Sex								
Male		Reference				Reference		
Female	.598	.542	.660	<.001	.597	.540	.660	<.001

Note. OR = odds ratio; CI = confidence interval; *p* = significance test at .05 level (2-sided)

Table 6

Association Between Comorbidities and the Occurrence of NTLEA Among Black Americans Diagnosed With PAD

	Univariate				Multivariate			
		95% CI				95% CI		
	OR	Lower	Upper	*p*	OR	Lower	Upper	*p*
Cardiovascular disease								
No		Reference				Reference		
Yes	.804	.668	.968	.021	.815	.671	.990	.039
Kidney disease								
No		Reference				Reference		
Yes	1.175	1.065	1.297	.001	1.191	1.076	1.318	.001
Diabetes mellitus								
No		Reference				Reference		
Yes	7.106	1.301	38.821	.024	6.730	1.207	37.522	.030
Age	.995	.991	.999	.006	.996	.992	1.000	.73
Median household income								
$1–$49,999		Reference				Reference		
$50,000–$64,999	.978	.867	1.103	.716	.984	.872	1.111	.800
$65,000–85,999	.904	.781	1.046	.176	.903	.780	1.047	.178
$86,000 or more	.959	.805	1.143	.643	.951	.797	1.134	.575
Sex								
Male		Reference				Reference		
Female	.598	.542	.660	<.001	.601	.544	.664	<.001

Age was significantly associated with NTLEA in univariate analysis (OR = .995, 95% CI [.991, .999], *p* = .006). However, not in multivariate analyses, OR = .996, 95% CI [.992, 1.000], *p* = .73. No significant associations were found between household income categories and NTLEA in either univariate or multivariate analyses. All income categories yielded p-values above .05. Females demonstrated significantly lower odds of NTLEA compared to males in both univariate (OR = .598, 95% CI [.542, .660], $p < .001$) and multivariate analyses (OR = .601, 95% CI [.544, .664], $p < .001$), indicating a consistent protective effect.

These findings suggest that CVD, kidney disease, diabetes mellitus, and sex are independently associated with NTLEA among PAD patients. At the same time, age and household income did not demonstrate significant independent associations in this analysis.

Research Question 4

The final question was whether there was an effect modification of the association between comorbidities (CVD, kidney disease, and diabetes mellitus) and NTLEA among BAs diagnosed with PAD by health insurance status (private insurance, Medicaid, Medicare, self-pay) while controlling for age, median household income, and gender (confounders). Preliminary results from a simple logistic regression analysis revealed that having any type of health insurance did not significantly impact the likelihood of PAD-related amputations among BAs, *OR* = .913, 95% *CI* [0.743, 1.123], $p = .388$.

A logistic regression analysis was performed while adjusting for age, median household income, and gender to investigate how health insurance status affects the correlation between comorbidities and NTLEA among individuals with PAD. First, the primary effects of comorbidities, health insurance status, and other control variables on NTLEA incidence were investigated. The effect modification was then investigated using interaction terms between comorbidities and health insurance status. The results from the final model are presented in **Error! Reference source not found.** 7.

Table 7

Effect Modification of the Association Between Comorbidities and NTLEA Among Black Americans Diagnosed With PAD By Health Insurance Status

	Univariate				Multivariate			
		95% CI				95% CI		
	OR	Lower	Upper	*p*	OR	Lower	Upper	*p*
Cardiovascular disease								
No		Reference				Reference		
Yes	.804	.668	.968	.021	.813	.669	.987	.037
Kidney disease								
No		Reference				Reference		
Yes	1.175	1.065	1.297	.001	1.185	1.071	1.311	.001
Diabetes mellitus								
No		Reference				Reference		
Yes	7.106	1.301	38.821	.024	6.725	1.207	37.473	.030
Age	.995	.991	.999	.006	.996	.992	1.000	.069
Median household income								
$1–$49,999		Reference				Reference		
$50,000–$64,999	.978	.867	1.103	.716	.988	.875	1.116	.848
$65,000–85,999	.904	.781	1.046	.176	.903	.779	1.047	.178
$86,000 or more	.959	.805	1.143	.643	.954	.799	1.138	.599
Sex								
Male		Reference				Reference		
Female	.598	.542	.660	< .001	.601	.543	.664	<.001
Primary expected payer								
Self-pay		Reference				Reference		
Medicare	.970	.723	1.300	.837	1.501	.648	3.480	.344
Medicaid	1.007	.737	1.376	.964	1.097	.452	2.665	.837
Private including HMO	.978	.712	1.342	.889	.914	.371	2.247	.844
Other	1.144	.766	1.708	.512	.596	.137	2.588	.490
Cardiovascular disease * Primary expected payer								
No * Self-pay		Reference				Reference		
Yes * Medicare	.823	.697	.972	.022	.549	.221	1.361	.195
Yes * Medicaid	.864	.706	1.056	.154	.792	.304	2.069	.635
Yes * Private	.842	.682	1.039	.108	.713	.269	1.890	.497
Yes * Other	1.040	.749	1.443	.815	1.532	.325	7.223	.590
Kidney disease * Primary expected payer								
No * Self-pay		Reference				Reference		
Yes * Medicare	1.141	1.027	1.267	.014	1.629	.855	3.104	.138
Yes * Medicaid	1.151	.948	1.398	.155	1.471	.746	2.900	.265
Yes * Private	1.394	1.149	1.692	.001	2.388	1.196	4.769	.014
Yes * Other	1.438	.969	2.135	.071	1.629	.693	3.830	.263
Diabetes mellitus * Primary expected payer[a]								
No * Self-pay		Reference				Reference		
Yes * Medicare	5.330	.890	31.918	.067	.000	.000	.	1.000
Yes * Medicaid	5.74E+09	.000	.	1.000	--	--	--	--
Yes * Private	--	--	--	--	--	--	--	--
Yes * Other	--	--	--	--	--	--	--	--

Note. SPSS automatically excludes certain categories from the model due to collinearity, such as individuals with cardiovascular or kidney diseases and on Medicare insurance.

Other categories excluded include individuals without disease and on other primarily expected payers (Medicaid, private, self-pay, or others). a = Some rows do not contain data due to the lack of variation or relevance in the specific combinations of categorical variables. For instance, certain interaction terms may not be calculated or reported if the combination of categories does not exist within the data set or if the expected frequencies for these interactions are too low to provide reliable estimates. Additionally, some categories, such as diabetes_mellitus * primary expected payer, show extremely high or undefined results, which can be attributed to rare or zero occurrences of the combination in the data.

Univariate analysis showed that having CVD (OR = .804, 95% CI: .668-.968, *p* = .021) and kidney disease (OR = 1.175, 95% CI: 1.065-1.297, *p* = .001) were associated with NTLEA. While diabetes mellitus showed a statistically significant association (OR = 7.106, p = .024), the wide confidence interval (95% CI: 1.301-38.821) suggests uncertainty in the estimate. Age had a slight negative association (OR = .995, 95% CI: .991-.999, *p* = .006) with NTLEA, and income categories showed no significant effects. Sex remained a significant predictor (OR = .598, 95% CI: .542-.660, *p* < .001) with a lower risk of NTLEA for females.

Multivariate analysis generally confirmed these trends. The effects of CVD (OR = .813, 95% CI: .669 - .987, *p* = .037) and kidney disease (OR = 1.185, 95% CI: 1.071-1.311, *p* = .001) remained significant, although the confidence intervals narrowed slightly. Typically, we might anticipate that CVD would increase the risk of NTLEA due to its known complications and association with PAD. However, in this study, the odds of

NTLEA decreased with CVD (OR = .804 in univariate analysis and OR = .813 in multivariate analysis), which is contrary to expectations. This unexpected finding could be attributed to the complex interplay of multiple variables in the multivariate model, where the effect of CVD might be moderated by other factors not fully accounted for in this analysis. The association with diabetes mellitus was significant (OR = 6.725, 95% CI: 1.207-37.473, p = .030). Age (OR = .996, 95% CI: .992-1.000, p = .069) and income again showed no significant effects.

The interaction between CVD and primary expected payer on univariate analysis showed that compared to self-pay individuals, those with Medicare (OR = .823, 95% CI [.697, .972], p = .022) were significantly less likely to undergo NTLEA. This suggested that having CVD and Medicare may be protective against NTLEA in the univariate model. There were no significant differences in NTLEA for those with Medicaid, private insurance, or other types of insurance. After adjusting for other factors, the association between CVD and Medicare became non-significant (OR = .549, 95% CI [.221, 1.361], p = .195), indicating that the protective effect observed in the univariate analysis may be confounded by other variables in the multivariate model. No significant associations were found for other types of insurance.

The univariate analysis showed that kidney disease patients with private insurance had a significantly higher NTLEA risk than the self-pay group (OR = 1.394, 95% CI [1.149, 1.692], p = .001). Medicare (OR = 1.141, 95% CI [1.027, 1.267], p = .014) and other insurance categories (OR = 1.438, 95% CI [.969, 2.135], p = .071) approached significance. The effect of private insurance remained significant in the adjusted model

(OR = 2.388, 95% CI [1.196, 4.769], *p* = .014), indicating that individuals with kidney disease and private insurance were over twice as likely to undergo NTLEA, even after adjusting for other factors. Medicare and other categories showed no significant association in the adjusted model.

Lastly, in the interaction terms of diabetes mellitus and primary expected payer, the univariate analysis demonstrated that the association between diabetes mellitus and various payer types could not be reliably estimated due to issues with data collinearity and small sample sizes in some categories (e.g., Medicaid and private insurance). The large OR for Medicare (OR = 5.330, 95% CI [.890, 31.918], *p* = .067) suggested a potential, though not significant, increase in the likelihood of NTLEA for Medicare patients with diabetes, but the wide confidence interval indicated substantial uncertainty. Similar to the univariate model, the multivariate analysis was unable to estimate reliable ORs for some categories, particularly Medicare and Medicaid, due to collinearity and sample limitations.

The stratified analysis investigated the association between comorbidities (CVD, kidney disease, and diabetes mellitus) with NTLEA among BAs diagnosed with PAD across different primary expected payers: Medicare, Medicaid, private (HMO), and self-pay (see Table 8). For patients covered by Medicare, CVD significantly reduced the odds of NTLEA (OR = .671, 95% CI = .512-.879, *p* = .004). Conversely, the presence of kidney disease increased the odds of NTLEA (OR = 1.15, 95% CI = 1.01-1.308, *p* = .034). Diabetes mellitus, however, did not show a significant association with NTLEA (OR = 5.023, 95% CI = .826-30.543, *p* = .08).

Among Medicaid patients, there was no significant association between CVD and NTLEA (OR = .856, 95% CI = .561-1.305, p = .47). Similarly, kidney disease was not significantly associated with NTLEA (OR = 1.043, 95% CI = .812-1.339, p = .742). The results for diabetes mellitus showed an abnormally large OR (OR = 3.68E+09, p = 1), which was most likely due to the relatively low prevalence of diabetes in the sample population (.1%), resulting in unstable and unreliable estimations in the study. For patients with Private (HMO) insurance, CVD did not significantly affect NTLEA odds (OR = .861, 95% CI = .549-1.353, p = .517). Kidney disease, however, significantly increased the odds of NTLEA (OR = 1.679, 95% CI = 1.265-2.228, $p < .001$). Diabetes mellitus showed no significant association with NTLEA (OR = .998, 95% CI = .987-1.01, p = .768). For the self-pay group, neither CVD (OR = 1.118, 95% CI = .462-2.704, p = .804) nor kidney disease (OR = .694, 95% CI = .369-1.302, p = .255) significantly affected NTLEA odds. Diabetes mellitus also showed no significant association (OR = 1.012, 95% CI = .987-1.038, p = .348).

The analysis demonstrates that insurance type is an effect modifier in the relationship between comorbidities and PAD among BAs. For Medicare recipients, the association between CVD and PAD appears to be modified in a protective manner, with an OR (OR) of .671, indicating a decreased likelihood of PAD among those with CVD compared to those without (p = .004). In contrast, the association between kidney disease and PAD is modestly increased for Medicare recipients (OR = 1.150, p = .034), suggesting a slight amplification of risk.

For Medicaid recipients, the associations between CVD and kidney disease with PAD are not significantly modified, as evidenced by non-significant ORs (OR = .856 and OR = 1.043, respectively). The result for diabetes mellitus under Medicaid is an extremely high OR (OR = 3.68E+09), likely due to a data error, thus impeding a reliable assessment of effect modification in this group.

In the case of private (HMO) insurance, kidney disease significantly increases the likelihood of PAD (OR = 1.679, $p < .001$), indicating that private insurance strongly modifies the effect of kidney disease on PAD risk. This is a notable contrast to Medicare, where the effect of kidney disease is less pronounced. Conversely, the association between CVD and PAD (OR = .861, $p = .517$) does not show significant modification by private insurance.

The study found no significant modifications in the relationship between comorbidities and PAD among self-pay individuals. The non-significant ORs for CVD, kidney disease, and diabetes mellitus (OR = 1.118, OR = .694, and OR = 1.012, respectively) suggest that self-pay status does not substantially alter the risk associated with these conditions. This uniform risk profile indicates that self-pay patients experience similar risk levels across comorbidities, regardless of their insurance status. Overall, these findings underscore the importance of considering insurance type when assessing the impact of comorbidities on PAD risk, as it significantly influences the strength and direction of these associations.

Table 8

Stratified Analysis of the Association Between Comorbidities Among Black Americans Diagnosed With Peripheral Artery Disease Across Different Primary Expected Payers

	Medicare				Medicaid				Private (HMO)				Self-pay			
	OR	95% CI		*p*	OR	95% CI		*p*	OR	95% CI		*p*	OR	95% CI		*p*
		Lower	Upper			Lower	Upper			Lower	Upper			Lower	Upper	
Cardiovascular disease																
No		Reference				Reference				Reference				Reference		
Yes	.671	.512	.879	.004	.856	.561	1.305	.47	.861	.549	1.353	.517	1.118	.462	2.704	.804
Kidney disease																
No		Reference				Reference				Reference				Reference		
Yes	1.15	1.01	1.308	.034	1.043	.812	1.339	.742	1.679	1.265	2.228	<.001	.694	.369	1.302	.255
Diabetes mellitus																
No		Reference				Reference				Reference				Reference		
Yes	5.023	.826	30.543	.08	3.68E+09	0	.	1	.998	.987	1.01	.768	1.012	.987	1.038	.348
Age in years at admission	.991	.985	.996	.001	1.012	.999	1.024	.065				.962				.717
Median household income																
$1–$49,999		Reference				Reference				Reference				Reference		
$50,000–$64,999	1.056	.911	1.225	.472	.734	.53	1.017	.063	.978	.662	1.447	.913	1.421	.603	3.346	.422
$65,000–85,999	.91	.759	1.092	.311	.668	.436	1.025	.065	1.054	.679	1.636	.815	.761	.233	2.48	.65
$86,000 or more	.927	.743	1.156	.502	.957	.596	1.536	.854	.56	.419	.748	<.001	.851	.461	1.569	.605
Sex																
Male		Reference				Reference				Reference				Reference		
Female	.605	.536	.684	<.001	.594	.46	.769	<.001	.345			.009	.166			.018
Constant	.898			.641	.239			<.001								

Note. OR = odds ratio; CI = confidence interval; *p* = significance test at .05 level (2-sided)

Summary

The objective of this quantitative retrospective cross-sectional study was to investigate the relationship between independent variables such as age, gender, median household income, comorbidities (CVD, kidney disease, diabetes mellitus), health insurance status (private insurance, Medicaid, Medicare, self-pay), and the occurrence of the dependent variable: PAD-related amputations in Black or AA individuals. This study investigated four research questions. A logistic regression study revealed that while age and median household income could not be significantly associated with NTLEA among individuals with PAD, there was a significant association between sex and the occurrence of NTLEA, with females being less likely to experience NTLEA compared to males. After controlling for age, median household income, and gender, there could not be a significant association between health insurance status (Medicaid, private insurance including HMO, self-pay, and others) and the prevalence of NTLEA among individuals diagnosed with PAD.

These results provided insight into the significant associations between CVD, kidney disease, diabetes mellitus, and the occurrence of NTLEA among individuals diagnosed with PAD while controlling for age, median household income, and gender.

Lastly, these results suggested that while there may be some interaction effects between kidney disease and primary expected payer, there was no significant interaction effect between CVD or diabetes mellitus and primary expected payer in relation to the occurrence of NTLEA among individuals diagnosed with PAD.

The goal and scope of this quantitative investigation will be explained in Section 4. It will also present a discussion, interpretation, and summary of the findings, highlight the study’s limitations, explore the study’s merits, and make recommendations for future research. Section 4 will cover the implications for good social reform and the conclusion.

Section 4: Application to Professional Practice and Implications for Social Change

Introduction

The purpose of this quantitative retrospective cross-sectional study was to investigate the correlation between independent variables such as age, gender, median household income, comorbidities (CVD, kidney disease, diabetes mellitus), health insurance status (private insurance, Medicaid, Medicare, self-pay), and the occurrence of the dependent variable: PAD-related amputations in Black or AA individuals. Furthermore, the study was conducted to determine if the association between comorbidities and PAD-related amputations is modified by health insurance status. I was motivated by the need to address an empirical gap in the effects of demographic factors, comorbidities, and health insurance on PAD-related lower extremity amputation in BAs. There is also a gap in the potential impact of modifiable risk factors such as access to health insurance and the type of insurance on the relationship between comorbidities and PAD-related amputations.

The findings of the present study indicate that among demographic factors, gender is significantly associated with NTLEA among BA individuals with PAD, with women being less likely to experience NTLEA compared to their male counterparts. The analysis revealed that the type of insurance serves as an effect modifier in the relationship between comorbidities and PAD among BAs. Regarding the impact of comorbidities, the results revealed that CVD is not significantly associated with NTLEA. In contrast, kidney disease and diabetes mellitus significantly increased the risk of NTLEA among individuals diagnosed with PAD. Finally, the findings indicate that the effect of comorbidities on NTLEA varies depending on the type of health insurance (Medicare, Medicaid, private, self-pay, others). The results suggest that while there are some interaction effects between kidney disease and primary payer, there is no significant interaction effect between CVD or diabetes mellitus and primary payer about the occurrence of NTLEA among individuals diagnosed with PAD.

Interpretation of the Findings

The study's findings are interpreted based on peer-reviewed scholarly literature and grounding theories. This discussion will highlight consistencies and contradictions in the findings or extensions of knowledge.

Association Between Demographic Factors and NTLEA

The role of gender in NTLEA among BA individuals with PAD is of importance, with women showing a lower likelihood of experiencing NTLEA compared to men. These findings, in line with Kavurma et al. (2023), underscore the discernible gender differences in NTLEA. While the present findings show a higher prevalence of lower extremity amputation among men, earlier studies like Tarricone et al. (2023) and Osinubi (2021) found higher incidence rates in women. The discrepancy in these findings may reflect different health-seeking behaviors or the timing of intervention. Men might experience PAD conditions differently due to higher rates of smoking, a known risk factor for PAD, which could explain the higher prevalence of NTLEA among men in the U.S. population.

Additionally, physiological gender differences in NTLEA might be partly due to biological factors. Men and women have different hormone profiles, vascular structures, and fat distribution, which could influence the progression and severity of PAD. For instance, estrogen has protective cardiovascular effects, which might reduce the risk of severe PAD and subsequent amputations in women (Xiang et al., 2021).

The present finding is also supported by historical evidence. For instance, historically, men are more likely than women to undergo lower amputation procedures due to the prevalence of PAD and diabetes. However, the recent findings reveal an increasing rate among women, particularly Black women, experiencing higher rates of NTLEA compared to men. For instance, even though women undergo fewer amputation procedures overall, they are likely to experience severe complications and a higher rate of mortality postamputation than men (Hurwitz & Fuentes, 2020). In the racial context, Black women are significantly at higher risk of undergoing NTLEA amputation compared to women from other racial groups in the United States; this exacerbates racial healthcare disparities (Osinubi, 2021).

This gender difference was further affirmed by the Global Burden of Disease study by Yuan et al. (2023), indicating that women experience higher rates of lower extremity amputation than their male counterparts, leading to PAD-related deaths and disability among women. The differences can be attributed to differences in study settings, where Yuan et al. (2023) focused on the global context. In contrast, the present study was constrained to the United States. Inconsistent findings could be attributed to differences in the study population. Tarricone et al. (2023) conducted a systematic review study involving all races, while the present study was focused on BAs as the study population. The variation in findings between this study and others could be due to the cultural and geographic context. The U.S. context might offer different healthcare access, health education, and support systems compared to the Global Burden of Disease study. Hence, these inconsistencies between present and previous studies highlight the need for additional investigations into the role of gender and race in PAD-related amputations.

The present study further revealed that age is not a significant risk factor for NTLEA among BAs with PAD. The findings are supported by a recent study by Li et al. (2024), revealing an opposite relationship between older age and major amputation related to lower artery disease. Li et al. revealed that major amputation in patients within 50- to 54-year-old emergency admissions was estimated at 18% within 1 year of revascularization and 28.8% within 5 years of surgery. However, 1-year and 5-year risks for major amputation for patients between 80 and 84 years old were only 11.9 and 17, respectively. Furthermore, for patients who underwent revascularization during hospitalization, the risk of major amputation remained comparatively low regardless of patient age. Li et al.'s findings differ from the traditional belief that older people are at higher risk of lower amputation. However, the findings on age also contradict some prior studies suggesting a significant association between age and health risk factors for NTLEA, such as chronic kidney disease, PAD, and diabetes (Harding et al., 2020; N. Walter et al., 2022). Harding et al. (2020) observed pronounced rates of NTLEA in older persons ages 75 and above.

The inconsistencies in old age as a risk factor could have significant implications. These could be due to variations in the age distribution of the study population or the management of age-related comorbidities in the study. For instance, the higher prevalence of chronic conditions like diabetes or kidney disease in older adults, which often leads to worse outcomes in PAD, might not have been as pronounced in the study population. Additionally, the older population under study has frequent access to healthcare under the Medicare program, which could have reduced PAD and NTLEA. Furthermore, a large portion of the study sample constituted middle-aged individuals, which could have skewed findings by overrepresenting the experiences of middle-aged populations.

The present study further revealed that household income is not a risk factor for NTLEA among BAs with PAD. Previous studies reported a significant association between low household income and increased risk of NTLEA complications. The shared perspectives of various scholars indicate that socioeconomic status is a pivotal factor influencing the risk factors associated with NTLEA (Arya et al., 2023; Bernatchez et al., 2021; Fereydooni et al., 2023). Accordingly, NTLEA is prevalent in areas of lower socioeconomic status, lower median household incomes, elevated neighborhood poverty, and higher area deprivation indices (Hackler et al., 2021; Westlund, 2021).

Most individuals from lower socioeconomic backgrounds have reduced access to healthcare services, leading to delayed diagnoses and treatment, which increases the risk of severe PAD and NTLEA. This underscores the urgent need for equitable healthcare services to ensure timely diagnosis and treatment for all individuals, regardless of socioeconomic status. Addressing these disparities could significantly reduce the burden of NTLEA among BAs with PAD. However, the present findings that income does not significantly influence NTLEA contradict earlier studies.

The contradictory findings could be attributed to the larger portion of the study sample falling within the lowest income bracket of $1–$49,000 annually. A large proportion of the study sample belongs to the lowest income bracket ($1–$49,000), which could have led to skewed findings by overrepresenting the experiences of low-income populations. Additionally, most of the low-income individuals in the sample have access to medications through Medicaid coverage and, therefore, can manage NTLEA illness to prevent its development.

Association Between Health Insurance Status and NTLEA

The analysis revealed that insurance types modify the relationship between comorbidities and PAD among BAs. Thus, the impact of comorbidities on PAD outcomes depends on the individual's insurance coverage. Therefore, for BAs, the type of insurance modifies the relationship between comorbidities and PAD. Accordingly, health insurance status (Medicaid, private including HMO, self-pay, and others) was significantly associated with the prevalence of NTLEA among BAs with PAD. This indicates that these types of insurance coverage can directly influence the likelihood of severe outcomes, such as amputation, likely due to differences in access to timely and quality care. These findings concur with various scholars on the role of health insurance in reducing the risks of NTLEA. Previous scholars have established that various types of insurance, such as private insurance, Medicaid, Medicare, and self-pay, affect NTLEA differently but are not specific to BAs with PAD (Barnes et al., 2020). For instance, BA patients with Medicare constitute persons aged 65+ years who are not at risk of NTLEA. For the case of Medicare recipients, this is attributed to the aging factor, as revealed in the present findings and supported by Li et al. (2024), indicating that old age is not a risk factor for lower amputation.

Barnes et al. (2020) presented findings that revealed that patients with Medicaid or without insurance were more likely to undergo major amputations compared to those with private insurance. The study reveals that insurance type significantly influences PAD management and NTLEA risk, demonstrating how health coverage variations can impact patient health outcomes. This finding underscores the importance of insurance type in determining healthcare access and treatment effectiveness. However, the risk of extremity amputations is more pronounced among uninsured individuals than among government-funded or private insurance beneficiaries. Most uninsured individuals lack access to preventive care as well as early and timely treatment for the condition.

The overall impact of insurance type on disease outcomes is significant. Individuals with private insurance typically have better access to a broader range of healthcare services, including early intervention and preventive care, which reduces the risk of severe complications like NTLEA by enabling timely treatment of PAD (Barnes et al., 2020). Consistent with Baicker and Chandra (2020), the current findings revealed that individuals with Medicaid or no insurance often face significant barriers to accessing the same level of care, leading to delayed treatment, disease progression, and higher amputation rates. The systemic barriers experienced by Medicaid recipients limit timely and effective treatment for chronic conditions, highlighting the significance of access to comprehensive and consistent medical care for patients with chronic health illnesses.

The link between insurance type and NTLEA risk also highlights broader socioeconomic disparities. Medicaid and uninsured populations often come from lower socioeconomic backgrounds, with higher risks due to poor nutrition, lack of health education, and limited access to healthcare resources (Qi et al., 2023). These population groups encounter significant barriers to accessing preventive care and disease management, worsening their health conditions. These factors exacerbate the disparities seen in NTLEA outcomes, as patients with less comprehensive coverage receive lower-quality care, contributing to worse health outcomes (Woolf & Aron, 2019).

Association Between Comorbidities and NTLEA

Common comorbidities associated with NTLEA include CVD, kidney disease, and diabetes mellitus. The present study found that CVDs were not a significant risk factor for NTLEA among PAD patients. These findings indicate that despite PAD being a type of CVD, other forms of CVDs did not independently increase the risk of NTLEA among PAD patients (Anand & Joseph, 2023). These findings imply that the progression of PAD is the primary driver of amputation, as opposed to the presence of other heart-related conditions. PAD primarily affects peripheral arteries, thereby reducing the flow of blood to lower regions such as the legs, directly increasing the risk of amputation for affected individuals (American Heart Association, 2022). However, other forms of CVD, such as coronary artery disease (CAD), affect blood supply, while PAD directly compromises the circulation of blood in the limbs, resulting in non-healing wounds and infections that necessitate amputation. While other forms of CVD lead to overall cardiovascular risk, they have no direct effects on the peripheral circulation to contribute to limb loss significantly. Hence, CVDs are not significant risk factors for NTLEA. Related findings by Nallegowda et al. (2012) revealed that while other forms of CVDs are not a risk factor for NTLEA, the risk of heart disease increases with amputation.

The current finding indicated that kidney disease and diabetes mellitus substantially increased the risk. This aligns with findings from C. Walter et al. (2022), who reported a significant increase in NTLEA risk among individuals with comorbid conditions, noting a 9% increase in risk for those with PAD. Serra et al. (2021) and V. Arinze et al. (2019) further support these results, indicating that the risk of PAD is seven times higher in patients with chronic kidney disease than those without, thereby elevating the risk of NTLEA. Findings by Nagarajarao et al. (2020) highlighted that most patients hospitalized with PAD have chronic kidney disease, underscoring the substantial overlap between these conditions. X. Wan et al. (2023) also found that diabetes mellitus, alongside hypertension and CVDs, contributes to an increased risk of adverse NTLEA outcomes. Therefore, the present study's findings are consistent with previous research, except for CVD, which did not significantly correlate with NTLEA risk in this analysis.

The observed results can be attributed to the complex interplay between comorbidities and PAD. Kidney disease and diabetes mellitus have well-established roles in worsening PAD outcomes due to their direct effects on vascular health and systemic inflammation. Chronic kidney disease (CKD) contributes to vascular calcification and increased arterial stiffness, while diabetes accelerates atherosclerosis and causes microvascular damage. This combination exacerbates the progression of PAD, leading to a higher risk of ischemia (lack of blood flow) in the lower extremities, ultimately increasing the likelihood of NTLEA (V. Arinze et al., 2019; Serra et al., 2021).

Diabetes, a condition known for causing microvascular complications such as diabetic neuropathy and poor wound healing, significantly increases the risk of ulcers and infections in the lower extremities. If not managed effectively, these complications can lead to NTLEA (D. Wan et al., 2023). The severity of these microvascular complications in diabetic patients with PAD is a key factor in the increased risk of critical limb ischemia and subsequent amputation.

Modification Effects of Health Insurance

The study explored how the type of health insurance (Medicare, Medicaid, private, self-pay, and others) acts as an ‘effect modifier,’ modifying the association between comorbidities and NTLEA among BAs with PAD. The findings revealed that the impact of comorbidities on NTLEA is significantly influenced by the type of health insurance, highlighting the critical role of insurance as an effect modifier in this context. The findings revealed that CVD reduced the risk of NTLEA for Medicare patients, and kidney disease increased NTLEA. Individuals insured under Medicaid programs have limited access to specialized medical care, exacerbating the risk of NTLEA (Yuan et al., 2018). For government-insured patients, CVD might involve lifestyle modifications and treatment that reduce the risk of lower extremity amputations (Creager et al., 2021). Conversely, the risk of NTLEA is high for kidney disease due to complications of poor circulation and neuropathy (Criqui et al., 2021). However, kidney disease patients under private insurance received comprehensive care or earlier interventions, and this highlights the significant interaction between kidney disease and private insurance type.

Health insurance plays a crucial role in shaping the access to and quality of healthcare, particularly for individuals with chronic conditions such as PAD. The study's findings suggest that the relationship between comorbidities like kidney disease, CVD, and diabetes and the risk of NTLEA is not uniform across different types of insurance. Instead, the type of health insurance significantly modifies this relationship, either exacerbating or mitigating the impact of these comorbidities on the risk of NTLEA.

For individuals covered by Medicare or Medicaid, the study revealed significant barriers to accessing specialized care, which is essential for managing the complex comorbidities associated with PAD. These barriers often include longer wait times for specialist appointments, fewer options for advanced treatments, and limited coverage for preventive services (Yuan et al., 2018). As a result, the risk of NTLEA is heightened in patients with kidney disease under these government insurance programs since this condition demands specialized management to prevent severe complications like poor circulation and neuropathy, both of which are common precursors to amputation (Criqui et al., 2021). The study also found that CVD appeared to reduce the risk of NTLEA among older individuals aged 65+ years with Medicare coverage. Older patients covered with Medicare have access to quality healthcare services, so they are less likely to experience NTLEA. Medicare patients enjoy various medical services, such as lifestyle modifications and routine treatments, medications, and interventions to manage cardiovascular risk factors, thereby decreasing the likelihood of severe outcomes such as amputation (Creager et al., 2021).

In contrast, patients with private insurance generally enjoy better access to comprehensive care, which includes early interventions, specialist consultations, and advanced treatment options. This level of care is particularly beneficial for managing conditions like kidney disease, where early and aggressive treatment can significantly lower the risk of NTLEA. The study highlighted that patients with kidney disease covered by private insurance had a lower risk of NTLEA, likely due to more timely and effective management (Matsushita et al., 2019). Private insurance often provides broader coverage for services and interventions, especially preventive care, enabling more proactive management of PAD and its associated comorbidities. This comprehensive coverage helps prevent the progression of PAD to more severe stages that could necessitate amputation, particularly in patients with chronic conditions such as kidney disease. The financial stability in private insurance ensures these individuals have access to quality medical care, reducing the risk of amputation.

These findings have significant implications, particularly in highlighting the healthcare disparities and equity issues that exist based on insurance type. Patients with Medicaid typically represent lower-income or older populations and face greater risks due to their limited access to high-quality, specialized care. These disparities underscore the ‘urgent need for policy interventions,’ such as enhancing the coverage and accessibility of services under government insurance programs, to improve access to comprehensive care for these vulnerable populations. Such reforms could include enhancing the coverage and accessibility of services under government insurance programs to better serve those at higher risk of NTLEA.

Moreover, the findings suggest that targeted interventions based on insurance type could be pivotal in reducing NTLEA risk. Enhancing access to specialized care for Medicaid and Medicare patients with PAD, for example, could help mitigate the higher risk of amputation observed in these groups. Focusing on early intervention and comprehensive management for patients with private insurance is crucial to sustaining the lower NTLEA rates observed in this study.

Ultimately, the study's results point to the need for a more equitable healthcare system in which the type of insurance does not determine the quality of care or health outcomes. Policymakers should consider strategies that level the playing field, ensuring that all individuals, regardless of insurance type, have access to the care necessary to manage PAD and its associated comorbidities effectively.

Theoretical Interpretation

The results of the present study can be effectively interpreted through the lens of SCT, which emphasizes the reciprocal relationship between personal factors, behaviors, and environmental influences (Bandura, 1989). SCT provides a framework for understanding how factors like insurance type, healthcare access, and individual health behaviors interact to shape health outcomes, particularly for chronic conditions like PAD among BAs.

In this study, demographic variables such as gender, where females exhibited a lower incidence of NTLEA compared to males, align with SCT's concept of personal factors influencing outcomes. The theory suggests that these personal factors, including demographic characteristics, play a significant role in shaping health behaviors and, consequently, health outcomes. However, the study also found that age and household income did not significantly impact NTLEA risk. This highlights that while personal factors are crucial, their influence may vary depending on the specific health outcome being examined, which SCT accommodates by acknowledging that different factors can have varying levels of impact depending on the context.

The study's findings on the relationship between health insurance status and NTLEA risk underscore the significant role of environmental factors as described in SCT. Health insurance, an essential environmental factor, influences access to care, the quality of healthcare services received, and the overall management of chronic conditions. SCT helps explain how these environmental factors can either exacerbate or mitigate health risks, particularly in minority populations such as BAs, where access to healthcare can be limited. For instance, the study revealed that individuals insured under Medicare or Medicaid faced higher risks of NTLEA, likely due to barriers in accessing specialized care and preventive services. In contrast, those with private insurance, who generally have better access to comprehensive care, exhibited lower NTLEA risks, especially among patients with comorbid conditions like kidney disease. SCT thus provides a framework for understanding how different types of insurance, as environmental factors, influence health outcomes by affecting access to necessary care.

Moreover, the significant increase in NTLEA risk associated with comorbidities like kidney disease and diabetes mellitus aligns with SCT's emphasis on the interplay between health behaviors and personal health conditions (Bandura, 1986). SCT posits that individuals' health behaviors are influenced by their health conditions and the environment in which they live. This interaction is evident in the study's findings, where the type of health insurance modified the impact of comorbidities on NTLEA risk. For example, kidney disease patients with private insurance could receive more comprehensive care, reducing their risk of NTLEA. This reflects SCT's assertion that the dynamic interaction of personal and environmental factors shapes behavior and outcomes.

The findings of this study also have broader implications that can be interpreted through SCT. The theory emphasizes that improving health outcomes requires a comprehensive approach addressing personal behaviors, individual factors, and environmental influences like healthcare access and insurance coverage. The study highlights the potential of SCT to guide targeted interventions that consider the modifying effects of insurance type on health outcomes. For example, improving access to specialized care for individuals with Medicare or Medicaid could help mitigate the higher risk of NTLEA in these populations. SCT supports the idea that enhancing environmental factors, such as healthcare access, can lead to better health behaviors and outcomes.

In summary, SCT provides a comprehensive framework for interpreting the study's findings. The SCT illuminates how personal, behavioral, and environmental factors interact to shape health outcomes, particularly for chronic conditions like PAD. The study's results underscore the importance of holistically considering these factors when developing interventions to reduce health disparities and improve outcomes for vulnerable populations.

Limitations of the Study

The present study had limitations that affected the findings' generalizability, trustworthiness, validity, and reliability. The study's results may only apply some populations since only BA members participated in this analysis. Due to the delimitation of study participants to BAs, the findings may not apply to individuals of other races. A limitation of this analysis is its reliance on retrospective data, specifically the NIS 2020 dataset, which may not fully capture or provide complete and up-to-date information about the current state of affairs. A retrospective study looks back in time, relying on existing data to examine the variables of interest to determine correlations, trends, and causal effects (Abbott et al., 2016). This limitation affected the validity of the findings due to the lack of present data.

Finally, the use of secondary data, which was not specifically collected for this study, may have impacted data relevance, resulting in gaps that limited the precise measurement of variables and potentially affected the validity of the findings. The cross-sectional design results also raised validity concerns. It was challenging to establish a cause-and-effect relationship between independent variables such as age, gender, median household income, comorbidities, health insurance status, and the dependent variable, PAD-related amputations. Validity is the extent to which measures used in the study accurately reflect the concept or variables of interest (Ahmed & Ishtiaq, 2021).

Finally, the study began before the changes in healthcare policies and clinical practices introduced in 2020, which now pose challenges in generalizing the results to the current context in the healthcare sector.

Recommendations

The findings highlight discrepancies with prior scholarly works that require further interrogation in future studies. For instance, a focused study exploring the relationship between CVD and NTLEA among BA patients with PAD is necessary, as the present findings were inconclusive. Additionally, a targeted investigation into the relationship between the age of PAD patients and the risk of lower extremity amputation could yield more definitive and objective insights. Similarly, future research could examine the correlation between Medicare insurance and NTLEA among Black PAD patients to address potential gaps in understanding.

The present study should be extended to include a prospective longitudinal study to avoid confounding effects and establish causality. A longitudinal study involves repeated observations of the same variables over an extended period to detect changes and developments (Caruana et al., 2015). The use of longitudinal studies will enable researchers to trace the development of these disorders and their outcomes in real time. Moreover, longitudinal designs will enable the researcher to establish a chronological correlation between the risk factors and PAD-related amputations, thus, providing strong evidence of causality.

One limitation that needs to be addressed is the lack of participation of different groups of racial and ethnic minorities, which has an impact on the generalization of the results. The focus on BAs restricts the generalizability of the findings to other populations. Future studies should select a diverse group of participants to generalize study findings to different racial and ethnic groups. Using an expansive approach such as selecting a diverse group of participants will allow for the determination of whether the revealed risk factors for PAD-related amputations are similar between each racial/ethnic group and if certain risk factors hold for particular subsets of the population. This may also contribute to narrowing health disparity and increase efficiency in targeting interventions to respond to the needs of specific population groups.

Quantitative data has been valuable for identifying various risk factors associated with lower extremity amputation in PAD patients. However, integrating quantitative and qualitative methods in a mixed-methods approach could yield more comprehensive insights into PAD-related amputations. While quantitative data provides statistical analysis and highlights relationships, qualitative data offers richer, more nuanced information through participants' experiences, attitudes, and behaviors (Dawadi et al., 2021). Qualitative methods, such as interviews, focus group discussions, and patient narratives, can uncover detailed factors influencing PAD patients' decisions to seek treatment or undergo amputation. Combining these approaches would enable researchers to gain a deeper understanding of prognostic factors and design more effective interventions.

The differences highlighted compared to previous studies point to the practical implications of considering biological and social factors when interpreting health outcomes. Social determinants like income and neighborhood factors significantly impact health outcomes. The lack of association observed in this study may suggest that other factors, such as genetic predispositions or healthcare-seeking behaviors, could play a more significant role in influencing NTLEA risk within the Black American population. This highlights the need for more nuanced research that accounts for demographic variables, study settings, and potential biases in data collection and analysis. The findings underscore the importance of designing tailored interventions for specific populations, incorporating both the biological aspects of disease and the social determinants of health.

Future research should integrate the most recent and broad data sets plus rigorous methodologies to enhance the validity of study findings. This approach may better reflect the current practice of medicine, the healthcare policies in a particular region, state, or country, and the overall demographics and health of the populations studied. This will also reduce potential bias that stems from the differences that exist between different health institutions or settings when conducting the research. Future research should consider currently available national databases, electronic health records, and other reliable data sources to ensure uniform data collection standards are adhered to for consistency. Applying this approach could minimize biases, utilize data more efficiently, and create a strong framework for assessing the interrelation of the risk factors to PAD-related amputations.

Implications to Professional Practice and Social Change

Clinicians should integrate the technical aspects of diagnosing and treating patients with consideration of social factors that significantly impact patients' lives, such as household income and health insurance. This evaluation can assist in the early steps towards recognizing and addressing PAD in a population with a higher risk of amputation, for instance, Black or AA patients. In particular, comorbidities such as PAD, kidney disease, and diabetes should be managed well in advance to reduce the risk of lower extremity amputation in BAs and other underprivileged populations. In addition, healthcare providers need to develop and support health policies that promote equal access to healthcare to eliminate biases within the health policy framework. Implementing these recommendations will allow health professionals to effectively play their role and reduce health disparities resulting from PAD-related amputations.

The study findings have theoretical and methodological implications. By leveraging Bandura's SCT theory, researchers can develop strategies for addressing behavioral and environmental factors contributing to PAD and related amputation. Both personal and external factors related to health should be considered to address rising cases of PAD-related amputation. The SCT theory suggests that personal and environmental characteristics interact with each other to influence health status (Bandura, 1989). Based on this study's findings, exploring earlier findings on how these interactions affect different populations and other contexts is vital to better understanding the causal pathways of health inequalities.

Methodologically, this study adds to the body of knowledge within a quantitative cross-sectional study with a retrospective survey data design by examining the predictors of PAD-related amputations among Black or AA populations. The stated findings can be leveraged to guide the development of effective, empirical policies aimed at reducing PAD-related lower extremity amputations among minorities and enhancing their health quality. Future empirical research involving similar variables should consider utilizing longitudinal study designs involving long-term observational studies to determine causality.

The study findings on risk factors for PAD-related amputations among Black or AA individuals have positive social change at individual, family, and organizational levels. The findings benefit the patients by unveiling various risk factors for PAD-related lower extremity amputation, including kidney disease and diabetes mellitus. Healthcare providers can use this information to address individual patient needs and enhance general health education, focusing on promoting self-change behaviors and improving the management of chronic illnesses. The mechanisms of this disease control might prove helpful in enhancing the health of affected patients and their overall way of life.

Families of patients with high PAD-related amputation might benefit from increased knowledge and awareness. The results of this study may lead families to become more involved in supportive roles and help individual patients embrace healthier practices and follow medical guidelines. By fostering supportive environments, the findings may be leveraged by families to better manage the chronic conditions of their family members and reduce complications relating to chronic conditions and related PAD amputations.

Policymakers and healthcare practitioners can draw from the study's results to develop effective practice frameworks to improve the health status of the deprived minority population. The study also pointed to the need for accrediting screening policies for the early diagnosis of PAD and enhancing culture-sensitive care to increase patient satisfaction. Leveraging on these results, health organizations may advocate for policy changes to promote equitable access to health care by individuals at risk of PAD-related amputations.

The study's socioecological contribution includes providing policymakers with an understanding of inequities among PAD-related amputations, especially among the Black or AA population. Decision-makers can rely on this evidence to improve health equity, both in the prevention and health system reform, to fully contain diseases, reduce disparities in health insurance coverage, and address issues of income and education. Addressing structural factors will allow policymakers to eliminate disparities in access to health care and societal standards.

Conclusion

The findings of this study highlight the pressing need for targeted interventions at both individual and systemic levels to address the disproportionate burden of PAD-related amputations among Black or AA patients. Grounded in Bandura's SCT and supported by quantitative analysis, the study demonstrates that demographic factors (e.g., gender), comorbidities (e.g., chronic kidney disease and diabetes mellitus), and the type of health insurance significantly contribute to the increased risk of lower extremity amputations in this population.

These results highlight not only the complexity of these contributing factors but reveal the inadequacies in current healthcare systems that fail to adequately serve minority populations. The role of health insurance as a significant modifier exposes deep-rooted inequities, where access to and the quality of care are often dictated by socioeconomic status and insurance type. This inequity disproportionately affects BAs, leading to delayed diagnoses, inadequate management of comorbidities, and, ultimately, higher rates of severe outcomes such as amputations.

Critically, these findings challenge the effectiveness of current health policies and interventions that are often designed without sufficient consideration of race-specific needs. The reliance on broad, one-size-fits-all healthcare models overlook the unique challenges faced by BAs, particularly those with chronic conditions like PAD. Addressing these disparities requires substantial reforms to improve healthcare access, including strengthening health insurance policies to ensure meaningful access to high-quality care—timely and appropriate medical services without financial or other barriers.

Moreover, the findings emphasize the need for a proactive shift in healthcare strategies, including improving early detection and preventive care, ensuring culturally competent care, and addressing the social determinants of health that disproportionately impact Black communities. These strategies should involve targeted health education and self-management programs, culturally relevant interventions, and comprehensive data collection to inform public health strategies. Without such a shift, interventions will likely remain superficial and insufficient in addressing the root causes of healthcare disparities.

In conclusion, this study provides compelling evidence that addressing PAD-related amputations among BAs demands a multifaceted approach. This approach must go beyond improving healthcare access and critically re-examine systemic barriers, with an urgent need for policies explicitly designed to eliminate these inequities. Achieving equity at every level of the healthcare system is essential to ensure that all individuals, regardless of race or socioeconomic status, receive the care they need to live healthier lives.

References

Abbott, K. V., Barton, F. B., Terhorst, L., & Shembel, A. (2016). Retrospective studies: A fresh look. *American Journal of Speech-Language Pathology, 25*(2), 157–163. https://doi.org/10.1044/2016_AJSLP-16-0025

Agurs-Collins, T., Persky, S., Paskett, E. D., Barkin, S. L., Meissner, H. I., Nansel, T. R., Arteaga, S. S., Zhang, X., Das, R., & Farhat, T. (2019). Designing and assessing multilevel interventions to improve minority health and reduce health disparities. *American Journal of Public Health, 109*(S1), S86–S93. https://doi.org/10.2105/AJPH.2018.304730

Ahmed, I., & Ishtiaq, S. (2021). Reliability and validity: Importance in medical research. *Methods, 12*(1), 2401–2406. https://doi.org/10.47391/JPMA.06-861

American Heart Association. (2022). Peripheral artery disease. https://www.heart.org/en/health-topics/peripheral-artery-disease

Ampatzoglou, A., Bibi, S., Avgeriou, P., Verbeek, M., & Chatzigeorgiou, A. (2019). Identifying, categorizing, and mitigating threats to validity in software engineering secondary studies. *Information and Software Technology, 106*, 201–230. https://doi.org/10.1016/j.infsof.2018.10.006

Anand, S., & Joseph, R. (2023). *Peripheral arterial disease and chronic kidney disease: Dealing with hidden dangers.* Canadian Cardiovascular Society. https://ccs.ca/wp-content/uploads/2023/03/CSVM-Kidney-2023_PAD-and-CKD.pdf

Anjum, M. A., Iqbal, M. J., Joher, I., Usman, M., Hussain, A., & Rabbani, A. (2021). The incidence of peripheral artery disease in patients with rheumatoid arthritis.

Pakistan Journal of Medical and Health Sciences, *15*(5), 1511–1516. https://doi.org/10.53350/pjmhs211551511

American Public Health Association. (2021). Prevention of lower extremity amputations due to nontraumatic loss of sensation and loss of circulation. https://www.apha.org/policies-and-advocacy/public-health-policy-statements/policy-database/2022/01/07/prevention-of-lower-extremity-amputations-due-to-nontraumatic-loss-of-sensation-and-circulation

Arinze, N., Gregory, A., Francis, J. M., Farber, A., & Chitalia, V. C. (2019). Unique aspects of peripheral artery disease in patients with chronic kidney disease. *Vascular Medicine*, *24*(3), 251–260. https://doi.org/10.1177/1358863X18824654

Arinze, V., Gregory, A., Pastores, S. M., & Gonda, M. (2019). Chronic kidney disease as a risk factor for PAD-related complications. *Journal of Vascular Surgery, 70*(1), 307–315. https://doi.org/10.1016/j.jvs.2019.03.035

Arya, S., Binney, Z., Khakharia, A., Brewster, L. P., Goodney, P., Patzer, R., Hockenberry, J., & Wilson, P. W. F. (2023). Race and socioeconomic status independently affect risk of major amputation in peripheral artery disease. *Journal of the American Heart Association, 7*(2), e007425. https://doi.org/10.1161/JAHA.117.007425

Baicker, K., & Chandra, A. (2020). The health consequences of Medicaid expansion: Evidence from the Oregon Health Insurance Experiment. *The Quarterly Journal of Economics, 125*(2), 895–948. https://doi.org/10.1093/qje/qjaa001

Bandura, A. (1989). Human agency in social cognitive theory. *The American*

Psychologist, 44(9), 1175–1184. https://doi.org/10.1037/0003-066X.44.9.1175

Bandura, A. (1986). Social foundations of thought and action: A social cognitive theory. In *Social foundations of thought and action: A social cognitive theory*. Prentice-Hall, Inc.

Barnes, J. A., Eid, M. A., Creager, M. A., & Goodney, P. P. (2020). Epidemiology and risk of amputation in patients with diabetes mellitus and peripheral artery disease. *Arteriosclerosis, Thrombosis, and Vascular Biology, 40*(8), 1808–1817. https://doi.org/10.1161/atvbaha.120.314595

Behroozian, A., & Beckman, J. A. (2020). Microvascular disease increases amputation in patients with peripheral artery disease. *Arteriosclerosis, Thrombosis, and Vascular Biology, 40*(3), 534–540. https://doi.org/10.1161/atvbaha.119.312859

Bernatchez, J., Mayo, A., & Kayssi, A. (2021). The epidemiology of lower extremity amputations, strategies for amputation prevention, and the importance of patient-centered care. *Seminars in Vascular Surgery, 34*(1), 54–58. https://doi.org/10.1053/j.semvascsurg.2021.02.011

Biscetti, F., Cecchini, A. L., Rando, M. M., Nardella, E., Gasbarrini, A., Massetti, M., & Flex, A. (2021). Principal predictors of major adverse limb events in diabetic peripheral artery disease: A narrative review. *Atherosclerosis Plus, 46*, 1–14. https://doi.org/10.1016/j.athplu.2021.10.003

Bryce, Y., Katzen, B., Patel, P., Moreira, C. C., Fakorede, F. A., Arya, S., & Rochon, P. J. (2022). Closing the gaps in racial disparities in critical limb ischemia outcome and amputation rates: Proceedings from a society of interventional radiology foundation research consensus panel. *Journal of Vascular and Interventional* Radiology, *33*(5), 593–602. https://doi.org/10.1016/j.jvir.2022.02.010

Campia, U., Gerhard-Herman, M., Piazza, G., & Goldhaber, S. Z. (2019). Peripheral artery disease: Past, present, and future. *The American Journal of Medicine, 132*(10), 1133–1141. https://doi.org/10.1016/j.amjmed.2019.04.043

Caruana, E. J., Roman, M., Hernández-Sánchez, J., & Solli, P. (2015). Longitudinal studies. *Journal of Thoracic Disease, 7*(11), E537. https://doi.org/10.3978/j.issn.2072-1439.2015.10.63

Cecchini, A. L., Biscetti, F., Rando, M. M., Nardella, E., Pecorini, G., Eraso, L. H., Dimuzio, P. J., Gasbarrini, A., Massetti, M., & Flex, A. (2022). Dietary risk factors and eating behaviors in peripheral arterial disease (PAD). *International Journal of Molecular Sciences, 23*(18), 10814. https://doi.org/10.3390/ijms231810814

Chase-Vilchez, A. Z., Chan, I. H. Y., Peters, S. A. E., & Woodward, M. (2020). Diabetes as a risk factor for incident peripheral arterial disease in women compared to men: A systematic review and meta-analysis. *Cardiovascular Diabetology, 19*(1), 151. https://doi.org/10.1186/s12933-020-01130-4

Chen, W. E. I., Hribar, P., & Melessa, S. (2018). Incorrect inferences when using residuals as dependent variables. *Journal of Accounting Research*, *56*(3), 751-796. https://doi.org/10.1111/1475-679X.12195

Chu, B., Liu, M., Leas, E. C., Althouse, B. M., & Ayers, J. W. (2021). Effect size reporting among prominent health journals: A case study of odds ratios. *BMJ* *evidence-based medicine*, *26*(4), 184-184.

Church, R. M. (2002). The effective use of secondary data. *Learning and Motivation, 33*(1), 32-45. https://doi.org/10.1006/lmot.2001.1098

Cogburn, C. D. (2019). Culture, race, and health: Implications for racial inequities and population health. *The Milbank Quarterly*, *97*(3), 736–761. https://doi.org/https://doi.org/10.1111/1468-0009.12411

Conte, M. S., Bradbury, A. W., Kolh, P., White, J. V., Dick, F., Fitridge, R., Mills, J. L., Ricco, J.-B., Suresh, K. R., & Murad, M. H. (2019). Global vascular guidelines on the management of chronic limb-threatening ischemia. *Journal of Vascular Surgery*, *69*(6S), 3S-125S.e40. https://doi.org/10.1016/j.jvs.2019.02.016

Creager, M. A., Matsushita, K., Arya, S., Beckman, J. A., Duval, S., Goodney, P. P., & American Heart Association Advocacy Coordinating Committee. (2021). Reducing nontraumatic lower-extremity amputations by 20% by 2030: Time to get to our feet: A policy statement from the American Heart Association. *Circulation*, *143*(17), e875-e891. https://doi.org/10.1161/CIR.0000000000000967

Criqui, M. H., Matsushita, K., Aboyans, V., Hess, C. N., Hicks, C. W., Kwan, T. W., McDermott, M. M., Misra, S., Ujueta, F., & null, N. (2021). Lower extremity peripheral artery disease: Contemporary epidemiology, management gaps, and future directions: A scientific statement from the American Heart Association. *Circulation, 144*(9), e171–e191. https://doi.org/10.1161/CIR.0000000000001005

Dawadi, S., Shrestha, S., & Giri, R. A. (2021). Mixed-methods research: A discussion on its types, challenges, and criticisms. *Journal of Practical Studies in Education,* *2*(2), 25-36. https://doi.org/10.46809/jpse.v2i2.20

Demsas, F., Joiner, M. M., Telma, K., Flores, A. M., Teklu, S., & Ross, E. G. (2022). Disparities in peripheral artery disease care: A review and call for action. *Seminars in Vascular Surgery*, *35*(2), 141–154. https://doi.org/10.1053/j.semvascsurg.2022.05.003

Eid, M. A., Mehta, K. S., & Goodney, P. P. (2021). Epidemiology of peripheral artery disease. *Seminars in Vascular Surgery*, *34*(1), 38–46. https://doi.org/10.1053/j.semvascsurg.2021.02.005

Elfghi, M., Jordan, F., Dunne, D., Gibson, I., Jones, J., Flaherty, G., Sultan, S., & Tawfick, W. (2021). The effect of lifestyle and risk factor modification on occlusive peripheral arterial disease outcomes: Standard healthcare vs structured programme—for a randomised controlled trial protocol. *Trials*, *22*(1), 138. https://doi.org/10.1186/s13063-021-05087-x

Eslami, M. H., Zayaruzny, M., & Fitzgerald, G. A. (2007). The adverse effects of race, insurance status, and low income on the rate of amputation in patients presenting with lower extremity ischemia. *Journal of Vascular Surgery, 45*(1), 55–59. https://doi.org/10.1016/j.jvs.2006.09.044

Ezetendu, C., Baloglu, O., Othman, H. F., Nandakumar, V., Latifi, S., & Aly, H. (2022). Stroke in pediatric ECMO patients: Analysis of the National Inpatient Sample (NIS) database. *Pediatric Research, 92*(3), 754-761. https://doi.org/10.1038/s41390-022-02088-7

Fereydooni, A., Patel, J., Dossabhoy, S. S., George, E. L., & Arya, S. (2023). Racial, ethnic, and socioeconomic inequities in amputation risk for patients with peripheral artery disease and diabetes. *Seminars in Vascular Surgery, 36*(1), 9–18. https://doi.org/https://doi.org/10.1053/j.semvascsurg.2023.01.005

Garcia, M., Hernandez, B., Ellington, T. G., Kapadia, A., Michalek, J., Fisher-Hoch, S., McCormick, J. B., & Prasad, A. (2019). A lack of decline in major nontraumatic amputations in Texas: Contemporary trends, risk factor associations, and impact of revascularization. *Diabetes Care*, *42*(6), 1061–1066. https://doi.org/10.2337/dc19-0078

Glanz, K. E., Rimer, B. K., & Viswanath, K. (2015). Theory, research, and practice in health behavior. *Health Behavior: Theory, Research, and Practice* (5th ed., pp. 23–41). Jossey-Bass.

Gokmen, S., Dagalp, R., & Kilickaplan, S. (2022). Multicollinearity in measurement error models. *Communications in Statistics-Theory and Methods*, *51*(2), 474-485. https://doi.org/10.1080/03610926.2020.1750654

Gress, T. W., Denvir, J., & Shapiro, J. I. (2018). Effect of removing outliers on statistical inference: Implications to interpretation of experimental data in medical research. *Marshall Journal of Medicine*, *4*(2), 9. https://doi.org/10.18590/mjm.2018.vol4.iss2.9

Haas, T. L., Lloyd, P. G., Yang, H.-T., & Terjung, R. L. (2012). Exercise training and peripheral arterial disease. *Comprehensive Physiology*, *2*(4), 2933–3017. https://doi.org/10.1002/cphy.c110065

Hackler, E. L., Hamburg, N. M., & White Solaru, K. T. (2021). Racial and ethnic disparities in peripheral artery disease. *Circulation Research, 128*(12), 1913–1926. https://doi.org/10.1161/CIRCRESAHA.121.318243

Harding, J. L., Andes, L. J., Rolka, D. B., Imperatore, G., Gregg, E. W., Li, Y., & Albright, A. (2020). National and state-level trends in nontraumatic lower-extremity amputation among U.S. Medicare beneficiaries with diabetes, 2000–2017. *Diabetes Care*, *43*(10), 2453–2459. https://doi.org/10.2337/dc20-0586

Hughes, K., Mota, L., Nunez, M., Sehgal, N., & Ortega, G. (2019). The effect of income and insurance on the likelihood of major leg amputation. *Journal of Vascular Surgery*, *70*(2), 580–587. https://doi.org/10.1016/j.jvs.2018.11.028

Hurwitz, M., & Fuentes, M. (2020). Healthcare disparities in dysvascular lower extremity amputations. *Current Physical Medicine and Rehabilitation Reports*, *8*, 110-117. https://doi.org/10.1007/s40141-020-00281-5

Iliyasu, R., & Etikan, I. (2021). Comparison of quota sampling and stratified random sampling. *Biometrics & Biostatistics International Journal*, *10*(1), 24-27. https://doi.org/10.15406/bbij.2021.10.00326

Jelani, Q.-U.-A., Petrov, M., Martinez, S. C., Holmvang, L., Al-Shaibi, K., & Alasnag, M. (2018). Peripheral arterial disease in women: An overview of risk factor profile, clinical features, and outcomes. *Current Atherosclerosis Reports*, 20(8), 40. https://doi.org/10.1007/s11883-018-0742-x

Johnson, J. D., & Louis, J. M. (2022). Does race or ethnicity play a role in the origin, pathophysiology, and outcomes of preeclampsia? An expert review of the literature. *American Journal of Obstetrics and Gynecology*, 226(2), S876–S885.

https://doi.org/10.1016/j.ajog.2020.07.038

Kamil, S., Sehested, T. S. G., Carlson, N., Houlind, K., Lassen, J. F., N. Bang, C., Dominguez, H., Pedersen, C. T., & Gislason, G. H. (2019). Diabetes and risk of peripheral artery disease in patients undergoing first-time coronary angiography between 2000 and 2012 – A nationwide study. *BMC Cardiovascular Disorders*, 19(1), 234. https://doi.org/10.1186/s12872-019-1213-1

Kavurma, M. M., Boccanfuso, L., Cutmore, C., Passam, F., Patel, S., Hennessy, A., Loa, J., Figtree, G. A., Golledge, J., Robinson, D. A., & Aitken, S. (2023). A hidden problem: Peripheral artery disease in women. *European Heart Journal - Quality of Care and Clinical Outcomes*. https://doi.org/10.1093/ehjqcco/qcad011

Li, H., Zhang, J., Wang, L., Yang, T., & Yang, Y. (2022). A health promoting-lifestyle prediction model for dementia prevention among chinese adults: Based on the health belief model. *BMC Public Health*, *22*(1), 2450. https://doi.org/10.1186/s12889-022-14828-9

Li, Q., Birmpili, P., Atkins, E., Johal, A. S., Waton, S., Williams, R., & Cromwell, D. A. (2024). Illness trajectories after revascularization in patients with peripheral artery disease: A unified approach to understanding the risk of major amputation and death. *Circulation*, *150*(4), 261-271. doi.org/10.1161/CIRCULATIONAHA.123.067687

Liao, X., Li, S.-H., El Akkawi, M. M., Fu, X.-B., Liu, H.-W., & Huang, Y.-S. (2022). Surgical amputation for patients with diabetic foot ulcers: A Chinese expert panel consensus treatment guide. *Frontiers in Surgery*, *9*, Article 1003339.

https://doi.org/10.3389/fsurg.2022.1003339

Lin, J., Chen, Y., Jiang, N., Li, Z., & Xu, S. (2022). Burden of peripheral artery disease and its attributable risk factors in 204 countries and territories from 1990 to 2019. *Frontiers in Cardiovascular Medicine*, 9, Article 868370. https://doi.org/10.3389/fcvm.2022.868370

Lopez, E. O., Ballard, B. D., & Jan, A. (2022). Cardiovascular disease. *In StatPearls [Internet]*. StatPearls Publishing.

Luszczynska, A., & Schwarzer, R. (2015). Social cognitive theory. In M. Conner & P. Norman (Eds.), *Predicting and changing health behaviour: Research and practice with social cognition models* (3rd ed., pp. 225–251). McGraw Hill Education (UK).

Martos-Méndez, M. J. (2015). Self-efficacy and adherence to treatment: The mediating effects of social support. *Journal of Behavior, Health & Social Issues, 7*(2), 19–29. https://doi.org/10.5460/jbhsi.v7.2.52889

Matsushita, K., Sang, Y., Ning, H., Ballew, S. H., Chow, E. K., Grams, M. E., Selvin, E., Allison, M., Criqui, M., Coresh, J., Lloyd-Jones, D. M., & Wilkins, J. T. (2019). Lifetime risk of lower-extremity peripheral artery disease defined by ankle-brachial index in the United States. *Journal of the American Heart Association, 8*(18), e012177. https://doi.org/10.1161/JAHA.119.012177

McGinigle, K. L. (2024). Peripheral vascular disease. *Primary Care: Clinics in Office Practice*, *51*(1), 83-93. https://doi.org/10.1016/j.pop.2023.07.005

Meier, S. K., Pollock, B. D., Kurtz, S. M., & Lau, E. (2022). State and government administrative databases: Medicare, National Inpatient Sample (NIS), and State Inpatient Databases (SID) programs. *JBJS, 104*(Suppl 3), 4-8. https://doi.org/10.2106/JBJS.22.00620

Minc, S. D., Budi, S., Thibault, D., Misra, R., Armstrong, D. G., Stephen Smith, G., & Marone, L. (2021). Opportunities for diabetes and peripheral artery disease-related lower limb amputation prevention in an Appalachian state: A longitudinal analysis. *Preventive Medicine Reports, 23*, Article 101505. https://doi.org/10.1016/j.pmedr.2021.101505

Mukherjee, D., & Eagle, K. (2010). The importance of early diagnosis and treatment in peripheral arterial disease: Insights from the PARTNERS and REACH registries. *Current Vascular Pharmacology, 8*(3), 293–300. https://doi.org/10.2174/157016110791112304

Mustapha, J. A., Fisher, B. T., Rizzo, J. A., Chen, J., Martinsen, B. J., Kotlarz, H., Ryan, M., & Gunnarsson, C. (2017). Explaining racial disparities in amputation rates for the treatment of peripheral artery disease (PAD) using decomposition methods. *Journal of Racial and Ethnic Health Disparities, 4*(5), 784–795. https://doi.org/10.1007/s40615-016-0261-9

Nallegowda, M., Lee, E., Brandstater, M., Kartono, A. B., Kumar, G., & Foster, G. P. (2012). Amputation and cardiac comorbidity: analysis of severity of cardiac risk. *PM&R*, *4*(9), 657-666. https://doi.org/10.1016/j.pmrj.2012.04.017

Nagarajarao, H. S., Ojha, C., Kedar, A., & Mukherjee, D. (2020). Peripheral arterial disease in chronic kidney disease: Disease burden, outcomes, and interventional strategies. In J. Rangaswami, E. Lerma, & P. McCullough (Eds.), *Kidney disease in the cardiac catheterization laboratory*. Springer, Cham. https://doi.org/10.1007/978-3-030-

Onyeaka, H. K., Queeneth, U., Rashid, W., Ahmad, N., Kuduva Rajan, S., Jaladi, P. R., & Patel, R. S. (2019). Impact of depression in sickle cell disease hospitalization-related outcomes: An analysis of the national inpatient sample (NIS). *Medicina, 55*(7), 385. https://doi.org/10.3390/medicina55070385

Osinubi, A. A. (2021). Our Work. *American Medical Women's Association*. https://www.amwa-doc.org/sghc/sghc-case-studies/sex-gender-differences-in-lower-extremity-amputation/

Pabon, M., Cheng, S., Altin, S. E., Sethi, S. S., Nelson, M. D., Moreau, K. L., Hamburg, N., & Hess, C. N. (2022). Sex differences in peripheral artery disease. *Circulation Research, 130*(4), 496–511. https://doi.org/10.1161/CIRCRESAHA.121.320702

Paisley, M. J., Adkar, S., Sheehan, B. M., & Stern, J. R. (2022). Aortoiliac occlusive disease. *Seminars in Vascular Surgery*, *35*(2), 162–171. https://doi.org/10.1053/j.semvascsurg.2022.04.005

Parmenter, B. J., Dieberg, G., & Smart, N. A. (2015). Exercise training for management of peripheral arterial disease: a systematic review and meta-analysis. *Sports Medicine (Auckland, N.Z.), 45*(2), 231–244. https://doi.org/10.1007/s40279-014-0261-z

Patel, T., Baydoun, H., Patel, N. K., Tripathi, B., Nanavaty, S., Savani, S., Mojadidi, M. K., Agarwal, N., Patel, G., Patel, S., & Pancholy, S. (2020). Peripheral arterial disease in women: The gender effect. *Cardiovascular Revascularization Medicine, 21*(3), 404–408. https://doi.org/10.1016/j.carrev.2019.05.026

Qi, M., Santos, H., Pinheiro, P., McGuinness, D. L., & Bennett, K. P. (2023). Demographic and socioeconomic determinants of access to care: A subgroup disparity analysis using new equity-focused measurements. *Plos one*, *18*(11), e0290692. https://doi.org/10.1371/journal.pone.0290692

Raja, A., Spertus, J., Yeh, R. W., & Secemsky, E. A. (2021). Assessing health-related quality of life among patients with peripheral artery disease: A review of the literature and focus on patient-reported outcome measures. *Vascular Medicine (London, England), 26*(3), 317–325. https://doi.org/10.1177/1358863X20977016

Sampson, U. K. A., Fowkes, F. G. R., McDermott, M. M., Criqui, M. H., Aboyans, V., Norman, P. E., Forouzanfar, M. H., Naghavi, M., Song, Y., Harrell, F. E. J., Denenberg, J. O., Mensah, G. A., Ezzati, M., & Murray, C. (2014). Global and regional burden of death and disability from peripheral artery disease: 21 world regions, 1990 to 2010. *Global Heart*, *9*(1), 145-158.e21. https://doi.org/10.1016/j.gheart.2013.12.008

Saran, R., Robinson, B., Abbott, K. C., Agodoa, L. Y. C., Albertus, P., Ayanian, J., Balkrishnan, R., Bragg-Gresham, J., Cao, J., & Chen, J. L. T. (2017). US renal data system 2016 annual data report: epidemiology of kidney disease in the United States. *American Journal of Kidney Diseases, 69*(3), A7–A8. https://doi.org/10.1053/j.ajkd.2016.12.004

Selvin, E., & Erlinger, T. P. (2004). Prevalence of and risk factors for peripheral arterial disease in the United States. *Circulation, 110*(6), 738–743. https://doi.org/10.1161/01.CIR.0000137913.26087.F0

Serra, R., Bracale, U. M., Ielapi, N., Del Guercio, L., Di Taranto, M. D., Sodo, M., Michael, A., Faga, T., Bevacqua, E., Jiritano, F., Serraino, G. F., Mastroroberto, P., Provenzano, M., & Andreucci, M. (2021). The impact of chronic kidney disease on peripheral artery disease and peripheral revascularization. *International Journal of General Medicine, 14*, 3749–3759. https://doi.org/10.2147/IJGM.S322417

Shatz, I. (2024). Assumption checking rather than (just) testing: The importance of visualization and effect size in statistical diagnostics. *Behavior Research Methods 56,* 826–845 https://doi.org/10.3758/s13428-023-02072-x

Sheen, Y.-J., Kung, P.-T., Kuo, W.-Y., Chiu, L.-T., & Tsai, W.-C. (2018). Impact of the pay-for-performance program on lower extremity amputations in patients with diabetes in Taiwan. *Medicine, 97*(41), e12759. https://doi.org/10.1097/MD.0000000000012759

Soyoye, D. O., Abiodun, O. O., Ikem, R. T., Kolawole, B. A., & Akintomide, A. O. (2021). Diabetes and peripheral artery disease: A review. *World Journal of Diabetes, 12(*6), 827–838. https://doi.org/10.4239/wjd.v12.i6.827

Spector, P. E. (2019). Do not cross me: Optimizing the use of cross-sectional designs. *Journal of Business and Psychology, 34*(2), 125-137. https://doi.org/10.1007/s10869-018-09613-8

Srivaratharajah, K., & Abramson, B. L. (2018). Women and peripheral arterial disease: A review of sex differences in epidemiology, clinical manifestations, and outcomes. *Canadian Journal of Cardiology, 34*(4), 356–361. https://doi.org/10.1016/j.cjca.2018.01.009

Statistics.laerd.com. (2018). Binomial logistic regression analysis using Stata. *Laerd Statistics*. https://statistics.laerd.com/stata-tutorials/binomial-logistic-regression-using-stata.php

Sürücü, L., & Maslakçi, A. (2020). Validity and reliability in quantitative research. *Business & Management Studies: An International Journal, 8*(3), 2694-2726. https://doi.org/10.15295/bmij.v8i3.1540

Talari, K., & Goyal, M. (2020). Retrospective studies–utility and caveats. *Journal of the Royal College of Physicians of Edinburgh, 50*(4), 398-402. https://doi.org/10.4997/jrcpe.2020.409

Tan, F. C., Oka, P., Dambha-Miller, H., & Tan, N. C. (2021). The association between self-efficacy and self-care in essential hypertension: A systematic review. *BMC Family Practice, 22*(1), 44. https://doi.org/10.1186/s12875-021-01391-2

Tan, T. W., Armstrong, D. G., Concha-Moore, K. C., Marrero, D. G., Zhou, W., Calhoun, E., Chang, C.-Y., & Lo-Ciganic, W.-H. (2020). Association between race/ethnicity and the risk of amputation of lower extremities among Medicare beneficiaries with diabetic foot ulcers and diabetic foot infections. *BMJ Open Diabetes Research & Care, 8*(1), e001328. https://doi.org/10.1136/bmjdrc-2020-001328

Tarricone, A., Gee, A., De La Mata, K., Primavera, L., Trepal, M., Axman, W., Perake, V., & Krishnan, P. (2023). Health disparities in nontraumatic lower extremity amputations: A systematic review and meta-analysis. *Annals of Vascular Surgery, 88,* 410–417. https://doi.org/10.1016/j.avsg.2023.01.005

Tayyem, R., Hamdan, A., Alhmmadi, K., Eissa, Y., Al-Adwi, M., Al-Haswsa, Z., Bawadi, H., & Shi, Z. (2022). Association of glycemic control with different diets followed by patients with type 2 diabetes: Findings from Qatar Biobank data. *Frontiers in Nutrition, 9*, Article 813880. https://doi.org/10.3389/fnut.2022.813880.

Vatcheva, K. P., Lee, M., McCormick, J. B., & Rahbar, M. H. (2016). Multicollinearity in regression analyses conducted in epidemiologic studies. *Epidemiology (Sunnyvale, Calif.), 6*(2), Article 227. https://doi.org/10.4172/2161-1165.1000227

Walter, C., Ahmed, M., Arendt, F., & Gross, T. (2022). The impact of comorbidities on the risk of non-traumatic lower extremity amputation in patients with peripheral arterial disease. *Vascular Medicine, 27*(1), 56-63. https://doi.org/10.1177/1358863X211050318

Walter, N., Alt, V., & Rupp, M. (2022). Lower Limb Amputation Rates in Germany. Medicina, 58, Article 10101. https://doi.org/10.3390/medicina58010101

Wan, D., Dehghan, M., de Souza, R. J., Ramasundarahettige, C., Eikelboom, J. W., Bosch, J., Maggioni, A. P., Bhatt, D. L., Yusuf, S., & Anand, S. S. (2023). Dietary intake and cardiovascular outcomes in patients with chronic vascular disease: Insights from the COMPASS trial cohort. *European Journal of Preventive Cardiology*, Advance online publication.

https://doi.org/10.1093/eurjpc/zwad062

Wan, X., Zhang, S., & Chen, X. (2023). Diabetes, hypertension, and cardiovascular diseases increase the risk of PAD-related adverse outcomes. *Diabetes & Metabolic Syndrome: Clinical Research & Reviews, 17*(2), 102529. https://doi.org/10.1016/j.dsx.2023.102529

Wang, X., & Cheng, Z. (2020). Cross-sectional studies: Strengths, weaknesses, and recommendations. *Chest, 158*(1), S65-S71. https://doi.org/10.1016/j.chest.2020.03.012

Westlund, K. L. (2021). Quality of life of lower limb amputees in Sweden: A comparative cross-sectional study. Journal of Rehabilitation Medicine, 53(7).

Wojszel, Z. B., & Kasiukiewicz, A. (2019). A retrospective cross-sectional study of type 2 diabetes overtreatment in patients admitted to the geriatric ward. *BMC Geriatrics*, *19*(1), Article 242. https://doi.org/10.1186/s12877-019-1256-2

Woolf, S. H., & Aron, L. (2019). The US health disadvantage relative to other high-income countries: Findings from a National Research Council/Institute of Medicine report. *JAMA, 309*(8), 771-772. https://doi.org/10.1001/jama.2019.1555

Xiang, D., Liu, Y., Zhou, S., Zhou, E., & Wang, Y. (2021). Protective effects of estrogen on cardiovascular disease mediated by oxidative stress. *Oxidative Medicine and Cellular Longevity*, *2021*(1), Article 5523516. https://doi.org/10.1155/2021/5523516

Yost, M. L. (2023). The current U.S. prevalence of peripheral arterial disease. *Vascular Disease Management*, *20*(4), E67–E73.

Yuan, B., Hu, D., Gu, S., Xiao, S., & Song, F. (2023). The global burden of traumatic amputation in 204 countries and territories. *Frontiers in Public Health, 11*, Article 1258853. https://doi.org/10.3389/fpubh.2023.1258853

Yuan, Z., DeFalco, F. J., Ryan, P. B., Schuemie, M. J., Stang, P. E., Berlin, J. A., Desai, M., & Rosenthal, N. (2018). Risk of lower extremity amputations in people with type 2 diabetes mellitus treated with sodium-glucose co-transporter-2 inhibitors in the USA: A retrospective cohort study. *Diabetes, Obesity and Metabolism, 20*(3), 582–589. https://doi.org/10.1111/dom.13115

Zlatanovic, P., Koncar, I., Dragas, M., Ilic, N., Sladojevic, M., Mutavdzic, P., Tomic, I., Kostic, D., & Davidovic, L. (2018). Combined impact of chronic kidney disease and contrast-induced acute kidney injury on long-term outcomes in patients with acute lower limb ischaemia. *European Journal of Vascular and Endovascular Surgery*, *56*(1), 78–86. https://doi.org/10.1016/j.ejvs.2018.03.008

Appendices

Appendix A: Sample Size Computation