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The etiologies of lower limb amputations in minority communities and novel surgical techniques for no-option patients

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Thesis

THE ETIOLOGIES OF LOWER LIMB AMPUTATIONS IN MINORITY COMMUNITIES AND NOVEL SURGICAL TECHNIQUES FOR NO-OPTION PATIENTS

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ABSTRACT

Lower limb amputation is on the rise in the United States, and unfortunately, due to provider implicit racial bias, predisposed health conditions, lower socioeconomic status, and limited access to quality healthcare minority populations have an increased risk of developing diabetes and vascular diseases that cause increased rates of lower limb amputations and thereby reducing their overall health outcomes. Minority populations include African Americans/Blacks, Hispanics/Latinos, Indigenous Americans, Pacific Islanders, Native Hawaiians, and Asian Americans, however for this thesis the two populations of focus will be the African American/Black and Hispanic/Latino populations due to the vastly available data compared to other minority groups. This literature thesis titled *Etiologies of Lower Limb Amputations in Minority Communities and Novel Surgical Techniques for No-Option Patients* will dive into the primary causes of lower limb amputations in minority populations, discuss ways to prevent lower limb amputations in the African American/Black and Hispanic/Latino populations, provide insight on ways to improve health outcomes to prevent lower limb amputations & increase health outcomes after vascular reconstruction. This thesis will also discuss the newer option of LimFlow pDVA system for candidates whose only option is amputation

after exhausting all conventional options such as healthy eating and exercise. Moreover, this thesis will analyze whether this innovative LimFlow pDVA system is different from other already utilized vascular reconstructive surgical methods, like bypass and angioplasty, for improved blood flow and amputation prevention. These patients are also known as “no-option.” The term “no-option” is defined as being ineligible for surgical or endovascular arterial revascularization” to regain at minimum partial blood flow. Furthermore, patients where amputation is deemed to be the only available intervention are also known as “no-option. Additionally, this thesis will dissect the connection between primary chronic and predisposed health conditions of the African American/Black and Hispanic/Latino population such as diabetes, cardiovascular disease, Peripheral Arterial Disease (PAD), and Chronic Limb Threatening Ischemia (CLTI) and an individual’s increased risk of undergoing a single or double amputation. Provider implicit racial bias, lower socioeconomic status, and limited access to quality healthcare in minority populations will also be explored as contributing factors to the increased risk of lower limb amputations seen in these communities. Although research has shown that the LimFlow pDVA system seems to be a better alternative for “no-option” patients, there are some limitations that were mentioned. Literary findings that supported and opposed the two-part hypothesis were found to have several limitations which included gaps in the centers of revascularization, underrepresentation of minority groups in research trials, the discrepancy in the term minority, lack of recommended tests to the general population, use of small sample size, and minimal diversity in the LimFlow clinical trials noting the importance of improving these limitations to help decrease the rates of lower limb amputations and improve health outcomes in African American/Black and Hispanic/Latino communities.

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LIST OF ABBREVIATIONS

ABI...Ankle Brachial Index

AKA..Above the Knee Amputation

BKA..Below the Knee Amputation

BU...Boston University

CLTI...Chronic Limb-Threatening Ischemia

HRQoL...Health-Related Quality of Life

PAD...Peripheral Arterial Disease

pDVA..Peripheral Deep Vein Arterialization

SES..Socioeconomic Status

INTRODUCTION

Imagine losing one leg, both legs, one foot, or both feet. This is known as a lower limb amputation because this is the removal of any part of the lower extremity (*Lower Limb Amputations*, 2017). For this thesis, lower limb amputation refers to the removal of any part of the lower extremity. This is a life-changing procedure that can drastically affect the patient who received the amputation(s) as well as the caregiver of the patient. According to The Amputation Coalition, as of 2021, there are approximately 5.6 million people in the United States of America living with limb amputations ("5.6 Million++ Americans Are Living with Limb Loss and Limb Difference," n.d.). While 5.6 million might not seem like a significant population at this time, back in 2005, approximately 2 million people were living with limb loss and this rate was expected to double by the year 2050 according to Graham et al ("Estimating the Prevalence of Limb Loss in the United States," 2008). This means that before the year 2050 has arrived, the number of people living with amputations has approximately already doubled. These are general statistics that do not consider specifically lower limb amputations. For lower limb amputations, the statistics show that about 150,000 people have lower extremity amputations every year. These statistics are concerningly high but even higher for minority populations. In the United States, minority populations include any racial or ethnic group not of European heritage, such as African American/Black, Hispanic/Latino, Indigenous American, Pacific Islander, Native Hawaiian, or Asian American. For this literature review, only the difference between the African American/Black and Hispanic/Latino populations will be compared and analyzed to the White/Caucasian population due to the adequate scholarly research available on these specific groups.

The loss of one or both lower limbs, known as single or double amputations, can potentially be a life-altering procedure for most people due to the negative impacts on daily quality of life factors, such as standing, walking, running, or driving a car. The need to improve quality of life can be a primary reason why researching and analyzing the topic of lower limb amputations is of utmost importance. According to Sosnowski et al., the phrases 'having an enjoyable life' and 'acquiring pleasure from lifestyle' were previously used to describe quality of life. Today, by contrast, quality of life is defined as a statistical index based on multiple parameters – economic-related, health-related, and environmental-related to an individual's or group's life conditions. This elaborate definition by Sosnowski et al. relates to Health-Related Quality of Life, also known as HRQoL (Sosnowski et al., 2017). HRQoL can include several attributes such as post-operative maintenance, maintenance of chronic illnesses if applicable, and the number of times someone is at the doctor's office weekly. Amputation is surgery that requires not only additional funds for rehabilitation, but also prosthetic creation, management, and maintenance which can be costly (Lefebvre & Lavery, 2011). Furthermore, this topic is of significance not solely because it affects one's quality of life, but because there are still many health disparities that need to be researched in regard to health outcomes addressed and closed through equity of access to health, which includes amputation prevention interventions as well as innovative surgical interventions such as the LimFlow pDVA system.

LimFlow pDVA system is different from other blood flow procedures such as bypass and angioplasty, the two main surgical options for amputation prevention as well as other endovascular techniques. Unlike these other blood flow procedures, the LimFlow pDVA system is a permanent option for non-reconstructable arteries (*Preventing Amputation of the Foot*, n.d.). This is significant because once a patient undergoes a surgery as significant as a bypass and an angioplasty, the goal is for the patient to have increased blood flow to the lower extremity, less pain, and a better quality of life. This literature thesis titled *Etiologies of Lower Limb Amputations in Minorities and Novel Surgical Techniques for No Option Patients* will dive into the causes of lower limb amputations in African American and Hispanic populations, talk about ways to prevent lower limb amputations in the African American and Hispanic populations, provide insight on ways to improve health outcomes to prevent lower limb amputations & increase health outcomes after vascular reconstruction for African Americans and Hispanic population. In addition, this thesis will discuss the newer option of the LimFlow pDVA system for candidates whose only option is amputation while analyzing whether this innovative LimFlow pDVA system is different from existing surgical methods, like bypass and angioplasty, for blood flow and amputation prevention. These patients are also known as "no-option.", which is defined as being ineligible for surgical or endovascular arterial revascularization" due to severe blood vessel blockage or total blood vessel blockage to regain at minimum partial blood flow (Clair et al., 2021). The LimFlow pDVA system is currently the last option for patients who are ineligible for surgical or endovascular arterial revascularization, like angioplasty or bypass, and will provide a way of preventing patients from having a lower limb amputation and preserving their HRQoL. In addition to the etiologies and discussion of the LimFlow pDVA system, this literature thesis will dissect the main chronic health conditions that increase African American and Hispanic populations' risk of lower limb amputations and the prevalence and incidence of other health complications that can add to one's increased risk of undergoing a single or double amputation.

This research topic stems from a personal encounter that triggered a passion for orthopedic surgery and vascular surgery, family members are part of the population with many chronic diseases, such as diabetes, cardiovascular disease, Peripheral Arterial Disease (PAD), Chronic Limb-Threatening Ischemia (CLTI), kidney disease, and neuropathy, that can potentially lead to amputation. In addition to these two experiences, I have also acquired the hands-on experience of working at a prosthetics and orthotics institution. Furthermore, research shows that "Black and Hispanic patients are at increased risk of poor limb outcomes when presenting at a similar stage of clinical severity" (Kalbaugh et al., 2022). The objectives of this research thesis are to provide a comprehensive review of the literature to thoroughly describe the nature and extent of the health disparities of lower limb amputation in African American and Hispanic communities, to explore the updated vascular surgical and restoration method to prevent amputation and to investigate the limitations of this newer method of vascular recovery and restoration. Additionally, as a woman who is part of the African American community, as well as one who values the Hispanic community as well, it is significant to dive deeper into these health disparities to understand what can be done to aid patients with similar backgrounds and of similar race in the future as a physician because everyone deserves quality healthcare and a good quality of life.

While this literature thesis will be analyzing already published literature, the published research is essential for evaluating this topic because the medical diagnoses of health conditions like diabetes and PAD, based on the data, have been shown to be higher in African American and Hispanic populations and lead to vascular complications, which positively correlates with lower limb amputations. Although there are lifestyle changes, such as diet and exercise and medical management options, for treatment for diabetes and vascular diseases like PAD or CLTI, there are many times that those options might not eliminate the need for surgical intervention for amputations to save lives. Additionally, this literature thesis can contribute to personal scientific and academic knowledge as well as the audience reading this topic to understand what diseases are more likely to cause an increased risk of lower limb amputation that can be used to evaluate and help future patients. Lastly, literature reviews recognize the latest developments in a specific area of study, make previously known information clear, explain the ramifications of the problem under analysis, make connections between theory and practice, and point out limitations in the existing literature, all of which enhance research for the future, even more so for amputation disparities in minority populations. The hypotheses are: 1) The intersectionality of provider implicit racial bias, predisposed health conditions, lower socioeconomic status, and limited access to quality healthcare create an intricate/complex network of barriers that increase African American and Hispanic populations' risk of developing diabetes and vascular diseases that cause increased rates of lower limb amputations and reducing their health outcomes. The term intricate or complex refers to how these four categories are intertwined with each other when discussing healthcare and how there can be major ripple effects from each; and 2) The LimFlow pDVA system is a system that provides an alternative to angioplasty and bypass and has a higher success rate than angioplasty and bypass, which can lead to more positive health outcomes post LimFlow procedure.

CHAPTER ONE

Healthcare is an ever-evolving discipline incorporating the treatment and prevention of medical challenges. In any situation, prevention is key, particularly regarding the health outcomes of patients. The greater the understanding an individual has of the importance of preventing health challenges, the more manageable those health challenges become. However, sometimes prevention may be hindered due to other uncontrollable factors such as race as well as the different aspects of the social determinants of health. Social determinants of health such as access to quality healthcare, access to quality education, and neighborhood context are important factors to highlight, and specific categories relating to this thesis will be emphasized. This first section will discuss the relationship between racial bias, predisposed health conditions, and lower limb amputations.

In the United States, the term minority can include racial and ethnic groups from the following backgrounds: Native Americans, Alaska Natives, Black or African Americans, Hispanics or Latinos, Asian Americans, Native Hawaiians, and Pacific Islanders. For this literature thesis the term 'Hispanic' will be used interchangeably when discussing the Hispanic populations, 'African American' or 'Black' will be used when discussing the African American population, and the term minorities or minority groups will mean both of these populations. The discovered data of these two minority groups will be compared to the White population. The term White or Caucasian will be used when speaking about the White, non-minority community. Although race is a factor that one cannot change about themselves, it is an aspect that can influence health outcomes.

For instance, certain races such as the African American and Hispanic populations are more likely to have specific predisposed health conditions. Predisposed health conditions can most likely be linked to genetics and family history. Predisposed health conditions are conditions that certain populations are more prone to obtain or develop based on their genetic makeup (*Definition of Genetic Predisposition - NCI Dictionary of Genetics Terms - NCI*, 2012). Predisposed health conditions are significant because many times when a patient develops a new disease, the disease might not appear haphazardly. The appearance of this new disease can be from genetics or family history. As reported by several different authors, Hispanic persons and African American persons both have a higher risk of developing type 2 diabetes mellitus due to Hispanic populations having the SLC16A11 gene and African Americans having the 11q, 12q, 13q chromosomes meaning these two minority groups have a predisposition to Type 2 diabetes mellitus, which has been shown to be a main contributor to decreased blood flow leading to lower limb amputations (Ng, 2015). Additionally, predisposed health conditions can help healthcare providers understand their patients more by analyzing their genetic makeup to include or subtract certain treatment interventions. Furthermore, if a patient knows they have a family history of a certain disease, they can be more likely to take action to try and prevent the worsening of the condition. According to the National Institute of Health, family history has a large role in common health conditions like cancer, cardiovascular disease, diabetes, autoimmune disorders, and other illnesses (Hernandez et al., 2006). As mentioned previously, diabetes is a health condition that minority groups are predisposed to. As it pertains to lower limb amputations, the diseases that are of main concern are diabetes and cardiovascular disease. According to The Department of Health and Human Services, "diabetes mellitus (diabetes) disproportionately affects underrepresented populations in the USA: while 13% of the general adult population has diabetes, disproportionately high rates of diabetes are found among American Indians/Alaska Natives (14.7%), Hispanics (12.5%), and non-Hispanic Blacks (11.7%) while lower rates are seen among non-Hispanic Asians (9.2%) and non-Hispanic Whites (7.5%)" (Haw et al., 2021). The two percentages of importance for this thesis are the Hispanic population percentage and the African American population percentage. It can be viewed that these two minority groups make up 11.7% and 12.5% of the 13% of the United States population that have diabetes. This means that of the approximately 331 million people in the United States, about 43 million people have diabetes. Of the 43 million with diabetes, these two minority groups make up around 10.3 million of the diabetic diagnoses. That is approximately 24% of the 43 million people with diabetes are Hispanic or Black and the White population makes up about 3.2 million of the diabetic population. 3.2 million versus 10.3 million can be seen as a significant difference. Given this interesting statistic and the predisposition of minority communities, it is important to note that diabetes can potentially lead to other medical risks, such as critical limb-threatening ischemia (CLTI) and peripheral arterial disease (PAD) are associated with an increase in lower limb amputations (Freisinger et al., 2017). From this information, it can be reasonably understood that if minority persons are more likely to develop diabetes, then they could be more likely to develop CLTI and/or PAD.

Peripheral arterial disease (PAD) deals with how well or poorly blood flow moves through the body, but even more specifically in the lower extremities (*Peripheral Artery Disease (PAD) - Symptoms and Causes*, n.d.). Critical limb-threatening ischemia (CLTI) deals with leg, foot, or toe pain and is a more severe form of PAD (Kim, 2022). Based on the statistics that state that diabetes mellitus (diabetes) disproportionately affects underrepresented populations in the USA, it can be reasonably inferred that if minority populations are more likely to have diabetes, CLTI, and PAD due to genetics or family history, then they are more likely to undergo an amputation; more specifically, a lower limb amputation (Haw et al., 2021). Both PAD and CLTI are serious health conditions that need to be addressed as quickly as possible. However, there is another factor that can contribute to the swiftness of diagnosing and treating these severe diseases. This factor is healthcare providers' implicit racial bias. Provider implicit racial bias as it pertains to amputations will be evaluated.

Provider implicit bias can be defined as judgments and stereotypes a provider could have based on race, ethnicity, culture, religion, or any other category that someone uses to define themselves (Vela et al., 2022). The specific category of race will be of focus, meaning the phrase 'provider implicit racial bias' signifies judgments and stereotypes a provider could have based on race. Furthermore, implicit means that something is not outwardly known or stated. In other words, it is hidden. It is imperative to highlight provider implicit racial bias when discussing the health of individuals because hidden judgments and stereotypes can harm patient safety and decrease health outcomes. These implicit racial biases by healthcare providers can be grouped into conscious or unconscious biases, meaning that providers can have either a conscious or unconscious racial bias toward patients. Over the years, scientific research has provided qualitative data that states that providers part of White providers do in fact, use camouflaged racism, and individuals from minority populations obtain less medical intervention and less than optimal medical care (Sim et al., 2021). Hacker et al state that African Americans are disproportionately affected by this disease while they are also less likely to be diagnosed and promptly treated and African Americans and Hispanics are 1.3 to two times more likely to have diabetes than White people (Hackler et al., 2021). Additionally, The Institute of Medicine released a landmark report titled *"Unequal Treatment: Confronting Racial and Ethnic Disparities in Health Care,"* which provides evidence that racial and ethnic minorities are treated differently from White populations in the United States healthcare system, specifically regarding diabetes and mortality when compared to White populations (Chow et al., 2012). While articles by the American Heart Association and other reputable sources discuss the negative dynamic between minority populations and the White population, authors Moore et al. discuss data surrounding the patient-provider relationship and how similarity or congruence meaning 'aspect of similarity' has a significant role in medical treatment (Moore et al., 2023). Moore and the participating authors presented peer-reviewed research data that stated that when healthcare providers and patients share at least one aspect of the same demographic traits, then the patient is more likely to have better-perceived quality of care from the provider, better health outcomes, as well as better satisfaction of the visit (2023). This is essential to pinpoint due to the increased health outcomes because the health outcomes can determine a patient's quality of life, as mentioned earlier. The perception of increased quality of care and better health outcomes could be due to the shared commonality between the minority patients and the provider who also is part of the minority population. When two or more persons share common ground, it can be easier to connect with them and understand them rather than judge them. To understand and connect, one must listen actively. Actively listening allows for the processing of expression, which is valuable for a healthcare provider to treat patients accurately, efficiently, and quickly. If providers are not listening to their minority patients and being assertive about prevention, then those patients can have worse health outcomes, such as an increased rate of developing diabetes. This information suggests that race contributes to negative health outcomes when the patient and provider are of different races. This connects to race and lower limb amputations because if a patient who is part of the minority community seeks medical treatment, but the provider is using race as a deterrent from properly educating, advising, and treating them for said medical condition, then this individual can develop negative health outcomes. More specifically, as mentioned previously, when treating a patient with diabetes CLTI, or PAD, many times, these health conditions do not appear haphazardly because they are predisposed to health conditions (*Definition of Genetic Predisposition - NCI Dictionary of Genetics Terms - NCI*, 2012). There are signs and symptoms that lead up to these life-changing diagnoses. An example of a factor that can lead to such a diagnosis as this is genetics due to predisposition. Without proper attention and treatment or prevention of these conditions, aspects like disease severity can increase, which have a significant role in health outcomes involving minority communities versus White communities. Examples of disease severity for diabetes can include but are not limited to numbness, burning, or tingling of the lower extremities, ulcer development, PAD, and CLTI. Other examples of disease severity include but are not limited to chest pains, shortness of breath, and blood vessel blockage Deshpande et al. discussed the complications of diabetes and endorsed that increasing age, being male, being African American, having peripheral neuropathy, and having chronic ulcers are all risk factors for lower extremity amputations (Deshpande et al., 2008). In agreement with Deshpande et al., Bellia et al. state diabetes enhances the likelihood of foot ulcerations and PAD, which both increase the odds of lower-extremity amputations, with the primary contributors being poor prognosis for foot ulcers, the degree of tissue loss, infections, presence of co-morbidities, and PAD (Bellia et al., 2022).

Without fast treatment of these diseases, minorities will continue to have disparities in amputations, as declared by (Hughes et al., 2014). Treatment may not solely refer to medication or intervention. It can include knowledge and access to different types of testing and basic health information. For example, PAD may not be as widely known in certain minority communities or a specific testing known as Ankle Brachial Index also known as ABI testing, might not be common knowledge to patients because it might not be the standard of care in all areas. Of note, ABI testing is not typically recommended for the general population (Criqui et al., 2021). There could be many reasons why ABI testing is not common knowledge. The factors could include lack of knowledge by the provider about ABI testing, outdated or nonrelevant information about

ABI testing, lack of training in ABI testing usage, and providers withholding ABI testing from minority patients due to their implicit racial bias. ABI testing is to measure the blood flow and blood pressure circulating through the lower limbs. While some scholarly articles state that race is independently associated with socioeconomic status, as mentioned by (Hughes et al., 2014), it is important to note that even a minority individual who can afford quality healthcare and is doing their best to take charge of their health might not truly receive quality healthcare because they are being discriminated against, judged, and stereotyped. The race of the patient, the implicit racial bias of the provider, and predisposed health conditions have a significant impact on the diagnosis and treatment of diabetes, PAD, and CTLI in minority groups. However, these are not the only factors that can increase the rate of lower limb amputations in African American and Hispanic populations. Socioeconomic status can affect the rate of lower limb amputations in these two specific populations as well. Socioeconomic status is the class of an individual and is mainly based on financial standing (*Socioeconomic Status*, n.d.). A figure in the article by Chernev and Chernev displayed the median average income as well as the mean income of different racial groups (Chernev & Chernev, n.d.). This figure displays the percentage of patients with major limb amputations and their associated education level. From this figure, the two groups with the highest percentage were the groups labeled ‘Below High School Education” and “High School Education”. These two groups made up 59.8% of the sample size being researched. This is greater than half of the sample size population that was used which was 127 persons. Although this is a small sample size, these statistics show that education level has an inversely proportional relationship with limb amputation (Chernev & Chernev, n.d.). As education level decreases lower limb amputation level increases. An aspect of financial standing is education. Access to quality education is a factor of socioeconomic status. Education is important because it determines other social determinants such as economic stability, access to quality healthcare, and neighborhood. Many aspects of life and health are connected. A better education can potentially lead to a higher-paying position. A better-paying job could provide individuals with sufficient funds to cover expenses for improved housing and healthcare. It was found that "patients with major limb amputation have a lower education level compared to the general population" (Chernev & Chernev, n.d.). Moreover, the Lancet Public Health, 2020 notes that physical health and well-being are inextricably tied to education. One of the strongest arguments for the significance of education as a health predictor is the available data presented by authors at Lancet Public Health, which declared, that life expectancy, morbidity, and health-related behaviors are all closely correlated with education, and academic achievement influences opportunities, employment, and wealth, all of which have a significant impact on health (The Lancet Public Health, 2020). Additionally, in relation to race, a figure in the literature by The National Center for Education Attainment portrays the education level statistics between racial groups (*Indicator 27: Educational Attainment*, n.d.). In the figure, the racial groups were on the x-axis, representing the dependent variable, and the percent was on the y-axis representing the independent variable. The bars labeled Black and Hispanic portrayed the highest percentage collectively compared to the percentage of other racial groups. The Black population in this study displayed that 15% of African Americans did not complete high school, while 31% of African Americans had only a high school degree. In the Hispanic column, 33% of persons did a percentage of people had not completed high school, and 28% had only a high school diploma. These statistics were compared to the statistics of the White population which showed only 8% of the White population had less than high school completion and 27% had only a high school degree. Additionally, for reference, other racial groups such as Asian, Pacific Islander, American Indian, and multi-race were also researched and showed a decreased percentage of persons with a high school diploma or less education. While these statistics are not particularly relevant for this literature thesis it is sufficient background to understand where the Hispanic population and the African American/Black population are on a larger scale when looking at multiple races. Furthermore, in other literature, it has been established that education level does affect health outcomes after lower limb amputations. “Patients who had lower levels of educational gain displayed lower rates of prosthesis adaptation post-amputation” (Nunes et al., 2014). A prosthesis can be an expensive journey to go through throughout someone’s life due to frequent visits, weight gain, or any other life event that can shift how the prosthetic leg or foot fits one’s body as well as the cost fluctuating. However, an amputation can drastically affect these opportunities, employment, and wealth. Depending on the field of work one has, an amputation can drastically affect their work life. Patients with careers that involve more walking and running like construction work, nursing, athletics, and fast food can be affected more than patients with careers where they are not walking or running often. Also, bosses and co-workers might not be as understanding as someone with an amputation which is considered a disability. A greater degree of education gave amputees access to more employment options and scheduling flexibility (Chernev & Chernev, n.d.). This is worth noting because having the freedom of increased job flexibility and scheduling can provide comfort and improve economic stability for an individual. Economic stability can be positively correlated with quality education as previously discussed. Economic stability can determine the quality of living, income, and ease of affordability. According to the National Institute of Health, "Income is associated with health outcomes across the life span, with higher income consistently predictive of better health." (National Academies of Sciences et al., 2023). Research has shown that individuals part of minority races and ethnicities tend to have lower incomes. The figure from the National Academies of Sciences et al about economic stability displayed the median and average household incomes based on race and ethnicity in the United States (National Academies of Sciences et al., 2023). Specifically, for the White population, the mean and median incomes were significantly higher than the Hispanic and Black populations. The Black population had a median and mean income of $48,000 and $71,000. The Hispanic population had a median and mean income of $57,000 and $80,000. The White population had a median and mean income of 74,000 and 105,000. $74,00 is a significant difference between 48,000 and 57,000, and 105,000 is a significant difference between $71,000 and $80,000. This graph supports the first part of the hypothesis about how lower socioeconomic status affects African American and Hispanic populations. These two groups, relative to the White community, are disproportionately affected by socioeconomic status and financial stability.

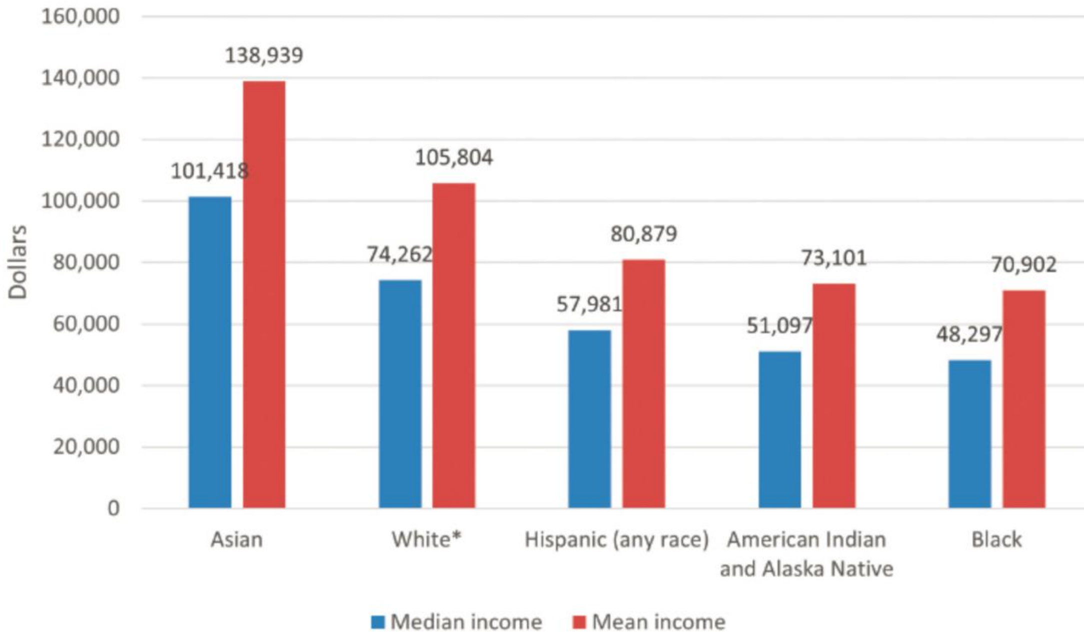

Figure 1. Mean and Median Income based on race (National Academies of Sciences et al., 2023**)**

It is important to discuss and analyze historical and modern methods of this income disparity because economic stability provides individuals with options. A better-paying career creates adequate funds to afford better housing accommodations and healthcare. Housing accommodations can also include the location/neighborhood of residence. Neighborhood correlates with economic stability and access to education. An individual's access to and completion of quality education can lead to increased financial stability, leading to greater funding for an enhanced quality of living as well as better access to quality healthcare. According to the Journal of the American Medical Association, a greater percentage of patients in underprivileged communities had significant leg amputations or passed away than those in non-disadvantaged neighborhoods. Regarding lower limb amputations, the lower the economic stability, the higher the rates of amputations. The Journal of the American Heart Association states that lower socioeconomic class markers and Black racial identity were linked to greater rates of major lower extremity amputation in metropolitan locations, which are home to the majority of patients having lower extremity amputation (Fanaroff et al., 2021). Moreover, education or lack thereof can potentially predict financial stability and how one can afford the basic needs of life such as insurance and location of residence. These data and statistics that display the connection between economic stability, education, and health outcomes are strong and can cause plausible concern to further evaluate the importance of researching ways to prevent lower limb amputations or provide revascularization of the blood vessels, which is of utmost importance in minority communities.

CHAPTER TWO

Race and socioeconomic status have been proven to influence health outcomes for minority patients when it pertains to lower limb amputations. Although socioeconomic status is one of the social determinants of focus, it is important to recognize and remember that all categories under the social determinants of health are pertinent to health outcomes such as access to quality healthcare. Access to quality healthcare will be the social determinant of focus in this section. As a reminder, the surroundings in which individuals live, learn, work, play, and worship are known as social determinants of health. These environments impact people's day-to-day activities and include the following categories: neighborhood and social context; economic stability; access to high-quality healthcare; and availability of high-quality education (*Social Determinants of Health - Healthy People 2030 | Health.Gov*, n.d.). It is significant to consider access to quality healthcare when exploring the differences in preventing certain health concerns in minority communities versus non-minority communities. Improving health outcomes and promoting and attaining health equity requires addressing the social determinants of health. The health of populations can be significantly impacted by health interventions, policies, and guidelines that seek to reduce health inequities. When thinking about access to quality healthcare, not only is predisposition significant to emphasize, but comorbidities are of importance as well. Comorbidities include two or more health conditions that coexist together and affect health outcomes (Valderas et al., 2009). In relation to lower limb amputations, an example of a fairly common comorbidity is diabetes and cardiovascular disease or diabetes and PAD. As displayed in Figure 4, there is a positive correlation between diabetes, cardiovascular disease, and PAD. These three conditions tend to be the primary health concerns that increase the incidence and prevalence of complications such as blindness, stroke, kidney disease, neuropathy, and amputation, especially in minority communities (Chow et al., 2012). Access to quality healthcare can allow for early diagnoses, treatment and management of chronic disease, and more health resources overall. Additionally, access to quality healthcare is essential because the number of people receiving lower limb amputations is increasing each year. Providers should be doing everything possible to promote preventative measures, patient education, vascular health, wound care and infection management, diabetes management, and early detection and treatment of chronic conditions are of utmost importance. According to an article in Sage Journals, early detection of many chronic diseases involves specialized exams that can be used to diagnose the condition even in its asymptomatic state—that is before any symptoms appear (*Early Detection of Disease and Scheduling of Screening Examinations - Sandra Lee, Hui Huang, Marvin Zelen, 2004*, n.d.). Early disease discovery could result in more treatments or increased survival times. Due to this potential, public health initiatives have been created that advise people to undergo screening exams regularly to identify certain chronic illnesses, such as diabetes, cancer, and heart disease (Valderas et al., 2009). Table 1 from the article titled “Disparities in Amputations in Minorities” from the Journal of Clinical Orthopedics and Related Research via the National Institute of Health provides an odds ratio analysis of amputation in minority communities to display the significance of this topic. It is specific to note the column labeled “Odds ratio expressing the increased rate of amputation among minority race and ethnicity” because it states that Black people were 1.6 times more likely to undergo a surgical procedure for PAD than White people and the White population were more likely to undergo revascularization (Lefebvre & Lavery, 2011). Additionally, under the odds ratio column, it was noted that Blacks and Hispanics were more likely to have an amputation rather than lower limb extremity revascularization. Overall, each statement in the odds ratio expressed that the data showed that the African American population and the Hispanic population were more likely to have an amputation. Another interesting part of Table 1 is that these studies were completed in the 1990s, however, the data is still comparable to studies

Table 1

Odds ratios of rate of amputation in minority race and ethnicity when compared with non-Hispanic whites found in the literature

Study	Author(s)	Population size	Odds ratio expressing increased rate of amputation among minority race and ethnicity
Variation in Utilization of Procedures for Treatment of Peripheral Arterial Disease	Tunis et al. (1993)	7080	The age-adjusted likelihood of having a procedure for peripheral was1.6 times higher in blacks than in whites; compared with patients who had angioplasty or bypass surgery, patients who had amputations were more likely to be black (OR, 2.5); compared with patients who had bypass surgery, patients who had angioplasty were more likely to be white (OR, 1.7)
Differences by race in the rates of procedures performed in hospitals for Medicare beneficiaries	McBean et al. (1994)	Approx 60,000 lower extremity amputations	With regard to approximately 60,000 admissions related to amputation based on ICD-9-CM procedure codes, black race was more likely to be correlated with admission for lower extremity amputation when compared with white race; the data provided in this study show a significantly higher risk of amputation (1.71 versus 5.54 in 1986 and 1.75 versus 6.33 in 1992) among blacks when compared with whites
The influence of race on the use of surgical procedures for treatment of peripheral vascular disease of the lower extremities	Guadagnoli et al. (1995)	19,236	White patients almost twice as likely to undergo arterial revascularization (AOR, 1.96) and almost three times more likely to undergo angioplasty (AOR, 2.86) Black patients (AOR, 2.06) to undergo amputation when compared with white patients
Racial differences in operation for peripheral vascular disease: results of a population-based study	Brothers et al. (1997)	2,961	Black women 7.6× more likely to undergo amputation when compared with other women and 1.3× more likely when compared with other blacks
Impact of race on the treatment for peripheral arterial occlusive disease	Huber et al. (1999)	51,819	Black patients more likely to undergo lower extremity amputations than whites (OR, 3.79)
Lower extremity nontraumatic amputation among veterans with peripheral arterial disease: is race an independent factor?	Collins et al. (2002)	11,494	A greater risk of amputation noted among Hispanics (OR, 1.4) and blacks (OR, 1.5) versus lower extremity revascularization
Racial differences in the incidence of limb loss secondary to peripheral vascular disease: a population-based	Dillingham et al. (2002)	27,149	Black race was associated with greater odds of loss a lower limb when compared with whites (OR, 2.4)

Open in a separate window

AOR = adjusted odds ratio.

Table 1. Different Studies and their Odds Ratio findings (from Lefebvre & Lavery, 2011)

today. For example, in the Journal of Vascular Surgery, Holman et al. state that a significantly lower percentage of Black/African American amputees had undergone revascularization compared to White amputees (Holman et al., 2011). This finding is similar to the statement from the study in 2002 by Collins et al as shown in Table 1.

It is essential to address health disparities because if more negative health outcomes are occurring in a certain group or groups of people, this affects the national healthcare budget and other resources that are provided to effectively research and provide medications and other procedures (Lefebvre & Lavery, 2011). Addressing health disparities can be seen as an issue that benefits everyone: locally, regionally, nationally, and internationally. Furthermore, it is important to discuss health disparities and amputation specifically because an amputation affects the quality of life. How they move, live, and survive are all impacted. An amputation can cause one to not be able to walk or do activities on their own or affect how an individual views themselves mentally. Sinha et al. provide support in the article, *Factors affecting the quality of life in lower limb amputees*, which declares a person's life and ability to function are profoundly altered by an amputation, rendering them permanently handicapped (2011). This changed situation affects amputees more than individuals who have lost an upper limb. Lower limb amputations happen more often than upper limb amputations. In wealthier nations [like the United States], vascular issues are the main reason for lower limb amputations, additionally, diabetic sores are a precursor to lower limb amputation, and diabetes and vascular issues are important health issues in developing countries (Sinha et al., 2011). A further aspect of health care that needs to be observed and discussed is the topic of insurance. Insurance is a critical factor in one's healthcare access. There are many different insurance types, however, based on socioeconomic status, as previously discussed, sometimes options are limited based on financial stability. Private insurance may be more expensive compared to Medicare, Medicaid, or being uninsured. Per data from the United States Census Bureau article volume in 2021, compared to white populations, minority populations were more likely to be uninsured as seen in the first figure (Branch & Conway, 2021). The bar graph in the first displays the percentage of uninsured patients based on race from the year 2021. The Hispanic group and the African American group displayed an extremely high percentage of people without health insurance. The Hispanic population had 17.7% without health insurance. The Black population had 9.6% of persons without health insurance. These percentages were observed compared to the White population who had only 5.7% of persons without health insurance. Health insurance is an essential part of healthcare and disease management. Insurance can provide a safety net of financial protection and security for adverse health events. As it pertains to lower limb amputations, health insurance can be crucial in situations such as the cost of a revascularization surgery to prevent amputation, prosthetics or prosthetic limbs after lower limb amputation, cost of repeat medical appointments for prosthetic fittings and psychological medical care post-amputation to name a few. Education affects one's financial stability, and financial stability can affect health insurance coverage, while ultimately affecting access to quality healthcare. In summary, health insurance is essential for enabling patients having lower limb amputations to have access to full medical treatment and social assistance. Health insurance eases financial constraints and guarantees that people receive the care they require to maximize their recovery, regain autonomy, and enhance their quality of life by paying for treatment, prosthetic limbs, rehabilitation, and continuing medical management. All things that are connected and have a ripple effect. Despite improvements over the years, there is still more action that needs to occur to provide the very best for racially diverse populations. This is why innovation is significant; it improves patient care for many different populations, not just one population.

It fosters scientific creativity to bring forth a skill, knowledge, or observation worth entertaining to continuously develop and improve medicine and science. For the subspecialties of Orthopedic Surgery and Vascular Surgery, this innovation is the LimFlow pDVA system to help prevent lower limb amputations for “no option" patients. The next session will provide a strong analysis into bypass, and angioplasty and how they compare to the LimFlow system.

CHAPTER THREE

According to the Columbia Department of Surgery (Columbia University Department of Surgery, 2012) and the Journal of Vascular Surgery (Goodney et al., 2009), surgical bypass occurs when a connected tube is placed with one end above the place of blockage and one end below the place of blockage so that the blood flow can ‘bypass’ the blocked/clogged area of the blood vessel usually in the leg or foot. Angioplasty refers to the procedure where a balloon is placed into the blocked blood vessel to open the narrow artery, then a stent is used to keep the artery open and allow for continued blood flow (*Angioplasty and Stent Placement - Peripheral Arteries -*

Discharge Information | Mount Sinai - New York, n.d.). Bypass and Angioplasty have been great options for helping increase blood flow to the lower extremities because the goal of these procedures is to increase blood flow to the areas downstream of the blockage to prevent necrosis of the tissue, which most likely results in lower limb amputations.

Over time, endovascular surgical procedures have increased (Guez et al., 2020). As presented in the article by the Journal of Roentgenology, two important figures displayed a line graph that shows the change in the volume of surgical versus endovascular techniques over a significant period of time from 2011 to 2016 as well as another line graph that showed the volume of endovascular procedures based on the medical specialties of Radiology, Vascular Surgery, Cardiology, and Other Physicians from 2011 to 2016 (Guez et al., 2020). In the line graph that shows the change in the volume of surgical versus endovascular techniques over a significant period, in 2011, the approximate number of surgical procedures completed in 2011 was around 60,000 while in 2016 the total approximate volume was closer to 50,000. This is almost a 10,000 decrease in the number of surgical procedures completed. While the decrease in surgical procedures has drastically decreased over time, the increase in endovascular techniques has increased drastically over time. In the line graph that showed the volume of endovascular procedures based on the medical specialties of Radiology, Vascular Surgery, Cardiology, and Other Physicians from 2011 to 2016, the endovascular procedures in the specialties of Vascular Surgery, as well as Cardiology, have continued to increase with Vascular Surgery having an increase from about 65,000 to 90,000 endovascular procedures and the Cardiology specialty increasing from 60,000 to 80,000 endovascular procedures a year. These are significant increases over time compared to the Radiology and other Physician groups which have had a decrease in the volume of endovascular procedures. The Radiology group has slightly increased from 2011 to 2016 going from 20,000 endovascular procedures to approximately 25,000 and other Physician groups have decreased from 30,000 endovascular procedures to approximately 25,000. These figures are significant because being that diabetes, cardiovascular disease, PAD, and CLTI are health conditions that increase one's risk of lower limb amputations, these are diseases that are included under the cardiology and vascular departments potentially meaning an increase in the number of persons needing endovascular surgery on their heart or lower extremities. Additionally, as mentioned earlier, by the year 2050, the rate of amputations is expected to double despite evolving and enhancing medical techniques and healthcare ("Estimating the Prevalence of Limb Loss in the United States," 2008). However, in recent decades, bypass and angioplasty have become less commonly used, although they are also considered endovascular techniques, and another option of endovascular technique has become more commonly adopted (Thukkani & Kinlay, 2015).

This more commonly adopted endovascular surgical procedure for amputation prevention is known as the LimFlow pDVA system. LimFlow is utilized in treating patients with no-option CLTI. This device known as the LimFlow pDVA system allows physicians to connect an artery in the calf to a vein near the foot to restore blood flow to the feet in patients with CLTI who are likely to have an amputation and are not suitable candidates for surgical bypass or angioplasty and who have been told and are expected to have a lower limb amputation (*A New Procedure Offers Hope to "no Option" Patients Facing Amputation Because of Severe Circulation Problems | CNN*, n.d.). The difference between LimFlow and bypass and angioplasty is that while bypass and angioplasty bypass the blockage of blood or simply open the blocked artery using a stent, LimFlow opens the blocked artery with a stent and catheter and connects the newly opened artery to a vein that is not blocked to reverse the flow of blood in that vein so the blood can go back to the foot and other areas of the lower extremity (*A New Procedure Offers Hope to "no Option" Patients Facing Amputation Because of Severe Circulation Problems | CNN*, n.d.). There are many parts to the LimFlow pDVA procedure. The materials and parts of the LimFlow pDVA system include an arterial catheter needle, the arterial catheter, the venous catheter, the stent graft system as well as the before and after of a patient who had the LimFlow procedure. Schreve et al describe the five-part LimFlow procedure including the ultrasound system, the extension cable set, the arterial & venous catheter, the valvulotome, and the stent graft:

1. Ultrasound: A transceiver box, a laptop computer, and a power source make up the LimFlow ultrasonic system. The transmit catheter receives a brief electrical shock from the system. The receiving catheter amplifies, filters, and streamlines the signal it receives. Both of the catheters may then be oriented thanks to the waveform presentation of the received signal on the laptop, which provides a visual representation of the received pulse's strength. The laptop's software allows for the adjustment of the receiver's gain as well as other settings (2019).

2. Extension Cable: Electricity is transferred between the LimFlow arterial and venous catheters and the LimFlow ultrasound devices via the LimFlow extension cords (2019).
3. Arterial & Venous Catheter: The 6.5-father arterial ultrasonography catheter has a useful length of approximately 100 cm. It is inserted through a sheath in the femoral artery, over a typical 0.014-inch guiding cable, and progresses to the tibial artery until complete arterial blockage is achieved. There are two purposes for the arterial ultrasonography catheter: locating the nearby veins and connecting to one of the nearby veins (2019).
4. Valvulotome: The goal of the valvulotome is to render the venous valves inoperable. A tool called a valvulotome is used to pass the crossing segment into the venous vessel by inserting it over the crossing wire. The distal point of the nitinol slicing spindle can be deployed by a push-pull operation. Up to a diameter of 4.5 mm, this cutting device self-centers in the venous vessel. Cutting of the vein valves is permitted once the blade component is forced past the valves, but cutting of the venous vessel is prevented by the arrangement of the real cutting blades at a smaller diameter than the permitted diameter of the cutting element. The device's overall outer diameter, including the deployable cutting element, is 4 Fr. The valvulotome is sterile and meant to be used just once (Schreve et al., 2019).
5. Stent Graft: Stent grafting is required to provide continuous blood flow via the newly formed vein-to-artery crossover. To accommodate physiological changes in

patient anatomy, the LimFlow stent graft product line offers a variety of self-expanding stent graft sizes and shapes, as well as a single delivery mechanism that works with any stent size. To generate finished stent-grafts, further forming and electro-spinning PTFE encapsulating processes are performed on the base laser-cut nickel-titanium alloy (nitinol) stent. The tube's interior functions as a 0.018″ guide wire space in the stent graft system of administration, and a flushing canal is proximally available via a check valve. The delivery device must be compatible with the 7-Fr sheath according to design input settings (Schreve et al., 2019). Figure 2 below shows the progress of a patient who underwent the LimFlow pDVA system at baseline meaning before the procedure and 6 months post meaning 6 months post LimFlow pDVA procedure.

Figure 2. Patient Progress who underwent LimFlow (Clair et al., 2021, p. 1)

While this novel surgical procedure sounds like it will and can save lives and reduce amputations as seen in figure 2, limitations include the cost of the procedure as well as research about the effects of this procedure greater than 12 months.

What makes LimFlow different from the other blood flow procedures such as bypass and angioplasty, the two main surgical options for amputation prevention as well as other endovascular techniques, is that it is a permanent option for non-reconstructable arteries, but also because is intended to bypass clogged arteries in the leg and pump blood back into the foot in a minimally invasive manner, saving major amputation, relieve pain, and accelerate the healing of wounds (*LimFlow — Designed to Heal Wounds and Prevent Amputation*, n.d.). This is significant because once a patient undergoes surgery as significant as a bypass and an angioplasty, the goal is for the patient to have increased blood flow to the lower extremity, less pain, and a better quality of life. Additionally, these surgical procedures are meant to last as long as possible, if not for life. However, this is not always the case. The data displays that bypass has been found to have increased morbidity over time as well as the need for re-intervention occurred more frequently, while the data presented for angioplasty procedure were shown to have a decreased morbidity and less frequent intervention, however, both methods of amputation prevention are not infallible (Darling et al., 2017). This information is slightly appalling because The Society for Vascular Surgery found that Black/African American and Latinx/Hispanic patients have a higher associated hazard of major adverse limb events after peripheral vascular intervention for chronic limb-threatening ischemia compared to white patients. Adverse events or complications could bring about more problems, even more for minority communities (Jaramillo et al., 2023) . Depending on what social determinants of health impact a person, these adverse events can be difficult to solve or manage. This means that amputation could potentially affect other health concerns one already has, about early statements about predisposition and comorbidities. By examining the social determinants of health, poorly controlled comorbidities, healthcare biases, and disease severity, it is clear that minority populations have a higher incidence and prevalence of amputations and are more likely to not have any other options other than lower limb amputations. According to Lefebvre & Lavery, both the African American population and the Hispanic population were identified as having a greater risk for amputation versus revascularization (Lefebvre & Lavery, 2011). Additionally, it is significant to analyze that if it was already shown and proven that minority communities are at a higher risk of having diabetes, cardiovascular disease, and PAD, then having to undergo revascularization can cause concern because these health conditions can affect healing post-surgery. This is because many times diabetes causes patients to have ulcers, lesions, and other sores that develop on the legs, feet, and toes, which could be due to lack of blood flow to the lower extremities. This lack of blood flow hinders oxygen from reaching the lower extremity making healing more difficult post-surgery, ultimately providing evidence that African Americans are associated with a 1.68 greater chance of lower extremity amputation and twice the chances for repeat amputation (Lefebvre & Lavery, 2011). One amputation is already draining; repeat amputations are devastating. Repeat amputations bring more concern for decreased healing and potentially mortality. This is what the LimFlow system is for. The LimFlow system is great for populations who have a difficult time healing, who are at a higher risk of amputation or repeat amputation, or who even with all healthcare access and financial stability are predisposed to severe disease progression, like minority populations. As shown in the Promise I study in Figure 7, the progression of wound healing post-surgery was fantastic. These are amazing results that patients with no other option would love to obtain. It is also significant to recognize that AKA (above-the-knee amputation) and BKA (below-the-knee amputation) are two of the five surgical operations most frequently linked to perioperative deaths and for patients who do have an amputation, the risk of peri-procedural and one-year post-surgery mortality is extremely high (Clair et al., 2021). The other types of bypasses, angioplasty, and other endovascular surgical procedures were found to have a 40% major amputation rate and a 20% mortality rate in 6 months (Clair et al., 2021). However, the LimFlow pDVA system had a high technical success rate, with a significant percentage of patients surviving free of major amputation at 12 months (Clair et al., 2021). While the LimFlow system provided strong evidence of success over the other conventional amputation prevention methods, there is still much research that needs to be conducted, which was stated in the few articles available about this new technique. LimFlow might serve as a strong option for minority patients in terms of preventing lower limb amputations due to the reduced collapsibility of the system and permanence, unlike angioplasty and bypass surgery (LimFlow — Designed to Heal Wounds and Prevent Amputation, n.d.). These past chapters have discussed how race, provider implicit bias, predisposed health conditions, lower socioeconomic status, and limited access to quality healthcare can negatively affect lower limb amputations and health outcomes. The next chapter will dive into the importance of obtaining positive health outcomes, what could be done to help achieve positive health outcomes from African American and Hispanic Populations regarding lower limb amputations, and the effect of negative health outcomes.

CHAPTER FOUR

As stated by Nedunchexhian et al, Ethnic and racial minorities are significantly more likely to have high-risk factors, have inadequate comorbidity management, present to doctors with severe disease outcomes, and have serious health problems ((Nedunchezhian et al., 2022). This statement portrays the importance of obtaining positive health outcomes for minority patients. The attainment of favorable health outcomes among patients represents a significant objective within healthcare, embodying not merely a metric of successful treatment but a foundational principle of healthcare's overarching mission. Central to healthcare philosophy is enhancing patients' well-being and improving their quality of life, rendering positive health outcomes the definitive gauge of efficacy. These outcomes encompass a multifaceted array of dimensions, spanning the physical, mental, and emotional spheres, alongside social functionality, and overall satisfaction with care provision. The realization of favorable health outcomes as it relates to a state wherein patients not only endure but flourish, enabling full engagement in daily activities like walking, running, biking, and driving and the pursuit of aspirations with robust vigor and no hindrances.

Relating to lower limb amputations, prevention of diabetes, cardiovascular disease, PAD, and CTLI are the beginning of creating positive health outcomes for

African American and Hispanic communities. An example of prevention for diabetes is the monitoring of food and beverage intake. The REACH program in Detroit is a prime example of improving health outcomes in the African American and Hispanic populations, and displayed a strong conclusion that stated, "A culturally tailored diabetes lifestyle intervention delivered by trained community residents produced significant improvement in dietary and diabetes self-care related knowledge and behaviors as well as important metabolic improvements." (Two Feathers et al., 2005). Healthy eating and drinking are the start to a healthier lifestyle and healthier outcomes for many populations. The REACH program is an example of an interactive intervention that can be duplicated and tailored toward African American and Hispanic populations around the United States.

Principal among the rationales underscoring the significance of favorable health outcomes is their direct correlation with the holistic happiness and life contentment experienced by patients. The advancement of health, whether through convalescence from illness or the management of chronic ailments, frequently culminates in heightened subjective well-being for individuals. Being free from pain, discomfort, and functional limitations affords individuals a more profound enjoyment of life, fostering sentiments of fulfillment and serenity. Positive health outcomes empower patients to reclaim power over their lives, facilitating active participation in many daily activities or extravagant activities.

Furthermore, the ramifications of favorable health outcomes extend to the broader societal landscape, exerting a palpable influence on communal well-being and economic prosperity. Individuals with robust health exhibit heightened productivity across personal and professional domains, thereby engendering constructive contributions to the labor force and communal fabric. Moreover, by curbing disease burden and disability, positive health outcomes alleviate strains imposed upon healthcare infrastructures and social support networks. This, in turn, liberates resources for the allocation towards other exigent societal needs while yielding long-term fiscal benefits by mitigating healthcare expenditures associated with preventable chronic maladies and their ensuing complications.

Additionally, favorable health outcomes precipitate the advancement of medical knowledge and innovation such as the LimFlow pDVA system. The LimFlow pDVA system is there as a net for patients who are able to regulate their diabetes and cardiovascular disease, but due to genetics are still have severe vascular issues despite tangible improvements like healthy eating, reduced sugar intake, and exercising. Successful treatment modalities furnish invaluable insights into the efficaciousness of interventions, thereby empowering healthcare practitioners to refine their methodologies and promulgate evidence-based guidelines. Through discerning analyses of triumphs and tribulations alike, researchers glean novel therapeutic paradigms and technological innovations, thereby fortifying the trajectory of healthcare's evolution to the tangible benefit of patients worldwide.

Positive health outcomes underscore the efficacy of collaborative care and interdisciplinary approaches. The optimization of patient outcomes invariably necessitates concerted endeavors from healthcare professionals spanning diverse specialties, synergistically supplemented by the active involvement of patients and their familial support structures. Instead of some White providers partaking in camouflaged racism when it relates to individuals part of minority populations and offering them less medical intervention and less than optimal medical care, there should be a cohesive teamwork focused on patient-centered care, healthcare providers collectively addressing minority patients' needs with comprehensive precision, fostering a culture of mutual accountability and dedication to maximizing positive health outcomes for all patients (Sim et al., 2021).

SPECIFIC AIMS

Specific aims of the following thesis include:

1. A comprehensive review of the literature to thoroughly describe the nature and extent of health disparities of lower limb amputation in African American and Hispanic Populations
2. Understand the relationship between race and lower limb amputations as it pertains to African American and Hispanic Populations
3. Understand the role access to quality healthcare contributes to lower limb amputations in African American and Hispanic Populations
4. Understand the relationship between socioeconomic status and lower limb amputations as it pertains to African American and Hispanic Populations
5. Exploration and analysis of the LimFlow pDVA system and its differences from other already utilized surgical methods, like bypass and angioplasty
6. Investigation into the limitations of the LimFlow pDVA system method of vascular recovery and restoration to potentially prevent amputation

METHODS

Methods of research are important to document and showcase research outcomes thoroughly. Similar to laboratory-based research, the methods section of a literature thesis is significant in the research process because it shows how the researcher gathered the necessary and relevant information to provide firm evidence of the answers to the research question. To duplicate research steps and methods for other researchers, scientists, and scientist-physicians the methodology is essential. Methodology includes the exact methods of obtaining the research and results. Moreover, this section discusses whether articles were in favor or opposition of the hypothesis or hypotheses and whether or not these articles confirmed the validity of the research and the credibility of the results, which is valuable.

For this literature thesis, multiple steps were completed to produce the needed material. First, the question: "What causes amputations?" was searched utilizing the Google Scholar database. This was a broad question to search, however, this is one of the questions that is the base of the thesis. It is imperative to know what exactly causes amputations to be able to gauge why certain populations are more affected by amputations than other populations. When researching this specific question, many sources of literature appeared, but the range was so broad that hand amputations, amputations in other countries, and amputations in the state of Minnesota were available. This search results were informative as it showed that amputations are regularly studied; however, there was a need to be more specific in the search to obtain further relevant material needed to thoroughly discuss and answer the questions about lower limb/extremity amputations. Subsequently, there was a need for a more targeted question, country, state, or timeframe. The time frame was the chosen category. Originally, the timeframe was set to any time, however, that was changed to 1980-2024 to allow for more recent and up-to-date articles to be shown. Once the timeframe was changed, multiple scholarly journals immediately displayed articles about lower limb amputations without having to explicitly state that lower limb amputations. Of these articles, keywords, and phrases such as diabetes, causes of lower limb amputation, understanding and treatment of patients with amputations, and life after amputations were presented.

Afterward, with the articles available that were relevant to lower limb amputations, a search of whether or not the journals where these articles came from were reputable sources. For example, the Hindawi Journal provided an article about lower limb amputations in patients with diabetes, however, before thoroughly reading the article, a deep dive into the journal partnerships and other resources was completed to assess Hindawi’s credibility. Other well-known scholarly literature and academic journals were shown to be partners with this journal company, so this article was used. This process was completed with other articles and journals as well. After researching the questions and the different journal articles, then reading and understanding the academic articles relevant to the topic took place.

The entirety of this process was completed using PubMed as well. The same question: “What causes amputations?” was the initial question utilized, however nonrelevant articles continued to be displayed. To have a more focused topic of articles, the question stem was changed to: “What causes lower limb amputations?” This question was better because it provided more articles specifically for lower limb amputations. PubMed had a greater selection of articles to choose from than the Google Scholar database, so for the remainder of the research, PubMed was the sole database used. Additionally, the use of the BU library section for finding articles was useful because it provided scholarly search databases for scientific articles. These resources were used thoroughly throughout the research process.

The next topic and question that was researched was LimFlow as well as "Does LimFlow work and if it does, how well does it work?" LimFlow is a unique name for this system. To gather thoughts and ideas to write a well throughout thesis, the current surgical methods were researched first by using the verbiage amputation prevention methods in the Google Scholar database. While researching the current methods of research, a research article titled Promise Study I was discovered. When reading through this article, the website of the official LimFlow website was included. The hyperlink of the official website was clicked, which transitioned to the LimFlow website. The website provided much information on what LimFlow was designed for, the clinical trial results, anatomy diagrams to help understand the LimFlow system, an educational video by patients and physicians, as well as information on the FDA approval of this newer minimally invasive procedure.

While specific questions were asked to find articles for this research topic, it is important to note that articles that supported the first part of the hypothesis were searched, chosen, and utilized. The articles used for the second part of the hypothesis about LimFlow provided great background information about LimFlow. Being that broad questions were searched, this was not intentional, however, the data from the selected articles all were in favor of race, lower socioeconomic status, and limited access to quality healthcare were shown to be causes of higher rates of lower limb amputations in minority communities. A few of the articles did challenge the second part of the hypothesis, however. Although the first part of the hypothesis was supported, it is significant to point out that the hypothesis stated that these factors were the primary causes, not simple causes. This is important to recognize because it displays the importance of having a strong hypothesis. Nonetheless, the hypothesis was fairly accurate, and the data supported this.

RESULTS

From the articles that proved the first part of the hypothesis, several statistics, findings, and gaps in the research were presented. The first major finding was that a significantly larger percentage (between 69%-93%) of minority patients were more likely to have lower limb amputations compared to the White population due to diabetes, PAD, and tissue infection. This finding signifies that amputations are more likely to occur when other chronic health conditions are present, meaning there need to be more preventative actions taken place earlier to ensure minority patients are receiving the treatment needed to gain control over diabetes, prevent PAD, and treat infection before it becomes deep and severe. The second major finding was that minority patients were less likely to receive revascularization intervention. This finding reveals the need for increased revascularization intervention while concerning post-revascularization adverse events. This is important because according to the Society for Vascular Disease, minority populations have a higher associated hazard of major adverse limb events after peripheral vascular intervention for CLTI compared to White populations. Other major findings were that socioeconomic status (SES) does indeed affect amputation outcomes. Less educated adults were noted to have worse general health, more long-term chronic conditions, and more functional limitations and disability. Additionally, it was discussed that neighborhoods and insurance, which are associated with SES, were possible factors of revascularization procedures or lack thereof. In fact, patients who were on Medicaid as well as patients without insurance were more likely to have an amputation. However, it was stated that not much research has been conducted on the neighborhood and amputation correlation to provide a strong statement about whether or not neighborhood stress impacts PAD, which can lead to amputations. This matters because it shows the depth of research already conducted and what more needs to be researched.

For the articles that opposed the first part of the hypothesis, the main statements that challenged the hypothesis were that "Black race and low socioeconomic status (SES) are independently predictive of major amputations in patients with peripheral artery disease and Black Americans were underrepresented in this specific trial comprising only 3.3% of all participants and that this trend towards greater amputations was not found in subsequent analyses.

In terms of the LimFlow system, it was found to have a higher success rate, which confirms the second part of the hypothesis. Although it seems to be a better alternative for "no-option" patients, there are some limitations. There is a lack of research being that it is such a new process. The LimFlow system was just approved by the FDA in

September 2023. Moreover, the limited research could potentially pose a hindrance due to the fact that there is not a robust selection of data available. This small sample of data could cause lack a of thorough understanding when trying to be applied to the general population, which is much larger than the sample size chosen. In the Promise I and Promise II studies, the sample size utilized was only 32- 105 patients and the success rates were 75%-96%. Although these statistics confirm the second hypothesis, this sample size is considerably small compared to the general population size as well as the number of individuals that receive amputation prevention surgeries each year, which is roughly 100,000 (*A Genetic Factor Is Linked to Long-Term Success of Leg Bypass Surgery | UC San Francisco*, 2011). Furthermore, the Promise I study utilized 66% males in the study, showcasing the need for an increase in the number of female-identified patients to have a more thorough understanding of this procedure based on gender.

Similarly, the Promise II study notes that 31.4% of the sample size were women, and 42.8% were Black or Hispanic. It is clear that the diversity increased for the Promise II study, however, more diversity is needed, which can be obtained over time (Shishehbor et al., 2023). To make firm conclusions about certain topics it is important to have a diverse set of data, which the LimFlow system currently does not have. The research gaps include gaps in the centers of revascularization, underrepresentation of minority groups in research trials, the discrepancy in the term minority, lack of recommended tests to the general population, and lack of accurate following and documentation of research participants.

DISCUSSION

While some articles supported the part of the hypotheses, others challenged the hypotheses, all these findings and limitations are significant because they all advance medical research and the health of individual populations. The hypotheses are: 1) The intersectionality of provider implicit racial bias, predisposed health conditions, lower socioeconomic status, and limited access to quality healthcare create an intricate/complex network of barriers that increase African American and Hispanic populations' risk of developing diabetes and vascular diseases that cause increased rates of lower limb amputations and reducing their health outcomes post-amputation. The term intricate or complex refers to how these four categories are intertwined with each other when discussing healthcare and how there can be major ripple effects from each; and 2) The LimFlow pDVA system is a system that provides an alternative to angioplasty and bypass and has a higher success rate than angioplasty and bypass, which can lead to more positive health outcomes post LimFlow procedure. Moreover, many articles show how much more work is needed to truly address the health needs of minority populations. For example, if a certain testing procedure is not utilized as often, then perhaps this method of testing should be used more heavily to address the lack of health services provided as well as take initiative on preventative methods for certain populations. Additionally, there was a discrepancy in the term minority. Some research articles had different populations labeled as minorities. For example, a few of the articles stated African American and Native American patients as minorities but did not include Hispanic patients or other ethnic groups that are considered minorities in the United States. This highlights the importance of the inclusion of all minority groups which can be further evaluated in the future, that way all evidence and support is in one place potentially. These limitations/gaps highlighted the importance of expanding the funding for research to be able to prolong research studies to be able to follow participants more closely and the need for continuous engagement and fostering of trust in minority communities as it pertains to research, so the research data can include these specific populations to increase their health outcomes.

CONCLUSION

In conclusion, the intersectionality of provider implicit racial bias, predisposed health conditions, lower socioeconomic status, and limited access to quality healthcare are an aspect that creates an intricate/complex network of barriers that increase African American and Hispanic populations' risk of developing diabetes and vascular diseases that cause increased rates of lower limb amputations and reduce health outcomes post-amputation. Also, the LimFlow system was shown to have a higher success rate than surgical methods for amputation prevention already utilized like bypass and angioplasty. The research provided firm evidence and data to make solid conclusions, however, there were still limitations presented, which included the centers of revascularization, underrepresentation of particular minority groups in research trials, the discrepancy in the term minority, lack of recommended tests to the general population, and lack of accurate following and documentation of research participants. In the scholarly literature, the phrase ‘centers of revascularization’ was not specified as a specific place in the body or if this meant actual surgical centers where the revascularization procedures occur. As it pertains to the underrepresentation of particular minority groups in research trials, these limitations provide ground for improvement in research terminology so all populations of minority individuals can have research specified toward their specific ethnic group, enhancement of revascularization centers, increased knowledge of testing, and increased observation of research participants. Furthermore, the LimFlow pDVA system provides promising results, however, due to the lack of long-term research and small sample size, these might not be the most solidified. A lack of research is a major barrier to progression and development in many different fields, ultimately emphasizing the value of funding and encouraging strong, diverse research initiatives. These gaps continue to push the essentiality of focusing on methods of implementation that can reduce the complexity of barriers minority communities face regarding amputations. By reducing these barriers, the potential effect would be a decrease in health conditions such as diabetes and PAD and, most importantly, lower limb amputations.

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