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ORIGINAL RESEARCH

Examining Sex-Based Differences Among Individuals With Peripheral Arterial Disease in Southwest Louisiana: A Secondary Data Analysis

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Abstract

Objective. The purpose of this study was to explore the relationship between sex and selected determinants of peripheral arterial disease (PAD) and the degree of symptom severity, initial types of treatments offered, and outcomes of men and women with PAD in southwest Louisiana. **Methods.** Subjects included all individuals with a PAD diagnosis determined by the International Classification of Diseases (ICD)-9 or ICD-10 coding. Data were queried and collected from January 1, 2015, to December 31, 2020, for secondary analysis from the Cardiovascular Institute of the South database. **Results.** The final cleaned and screened data set included 15,028 subjects. No sex-based difference in age at initial diagnosis was found. Surprisingly, 42% of women and 28% of men presented with 30% vessel occlusion (normal), while only 19% of women had total vessel occlusion when compared with men; both findings were statistically significant (P<.001). While no difference was noted between men and women for medical management, there was a statistically significant difference between groups in that men were more likely to undergo surgical repair. The most relevant finding was how the variable, symptom severity measured by color-flow duplex imaging scores, frequently negated any interaction or moderating effects of sex when added to the models. **Conclusion.** Findings indicate that this population is seeking and receiving care sooner than patients with similar disease in other parts of the country, regardless of sex. Moreover, treatment plans are being guided by the most robust diagnostic methods, mitigating adverse outcomes.

Introduction

Approximately 8.5 million individuals in the United States have peripheral arterial disease (PAD). This disease is estimated to affect over 230 million people worldwide, accounting for 7% and 5.6% of the U.S. and global populations, respectively.[1,2] Individuals over age 60 are at the highest risk for disease development and progression. By 2029, people aged 65 or older will comprise 20% of the total U.S. population, a 7% increase from 2010.[3] If the incidence of PAD rises in parallel with the aging population, an unprecedented financial burden will be placed on the U.S. healthcare system.[4,5]

Traditionally considered a male-dominant disease, in 2009, the mean prevalence of PAD was first reported to be greater among women (15.6%) when compared with men (13.4%).[6] Although shifting patterns of disease distribution have emerged over the past 2 decades, causing providers to question the known prevalence, presentation, development, and progression of select disease patterns, recent research findings suggest that while the prevalence of PAD continues to rise worldwide, in general, cases remain higher among women of all ages than men.[7] Conventional medical practices have led to the under-recognition of the disease's contribution to mortality rates among women, while findings of numerous research studies have suggested poorer outcomes for women when compared with their male counterparts with similar risk factors.[6,8-14]

There is a paucity of available population-based studies on sex-based differences and PAD. To date, no published studies include individuals with PAD who live in the southwest Louisiana region. In 2021, Louisiana ranked 50th for overall health outcomes and 41st in the nation for cardiovascular disease. Core measures influencing this ranking associated with the determinants of PAD include rates of smoking, obesity and physical inactivity, hyperlipidemia, hypertension, and type II diabetes mellitus, with each consistently exceeding national averages.[15-17] The purpose of this study was to explore the relationship between sex and selected determinants of PAD and the degree of symptom severity, initial types of treatment measures, and outcomes of men and women with PAD in southwest Louisiana.

Methods

The development of an interdisciplinary partnership with the Cardiovascular Institute of the South (CIS), the major cardiology group in southwest Louisiana, served as the foundation for conducting a population-based secondary data analysis using an extensive healthcare system database. Institutional review board approval from the University of Utah was granted in August 2020. A search was conducted for patients diagnosed with PAD as determined by the International Classification of Diseases (ICD)-9 or ICD-10 coding; therefore, a purposive sample was used. Data were queried and collected from January 1, 2015, to December 31, 2020. The electronic database initially provided access to approximately 30,000 patient records and 360,000 corresponding patient encounters, including hundreds of data points representing demographic, radiological, flow spectrometry, medication, laboratory, and health history information.

The sample size was determined by the number of patients in the database; all patients meeting inclusion criteria were included in the sample. Traditional power analysis to determine sample size was not applicable. Instead, for regression modeling and moderation analysis, the number of subjects (and factors such as the amount of variability in the data) determined how many variables could be included in each model. The final cleaned and screened data set included 12,000 to 15,000 subjects, establishing an appropriate sample size for all proposed models.

Demographic variables included sex, age, race, type of insurance, zip code (as a proxy for location), and marital status. Variables for the selected determinants of PAD included race, smoking history, and obesity as measured by body mass index (BMI) values. The timing of disease onset (age at initial diagnosis), the degree of symptom severity (color-flow duplex [CFD] imaging scores and ankle-brachial index [ABI] values), and the initial type(s) of treatment measures provided (medical management vs surgical management; bypass graft procedure) functioned as both independent and dependent variables while sex served as the moderating variable in the analysis process. Patient outcomes, operationalized as mortality (death within the study's time frame) and incidence of limb amputation secondary to PAD, functioned as the final dependent variable in the conceptual model (**Figure**).

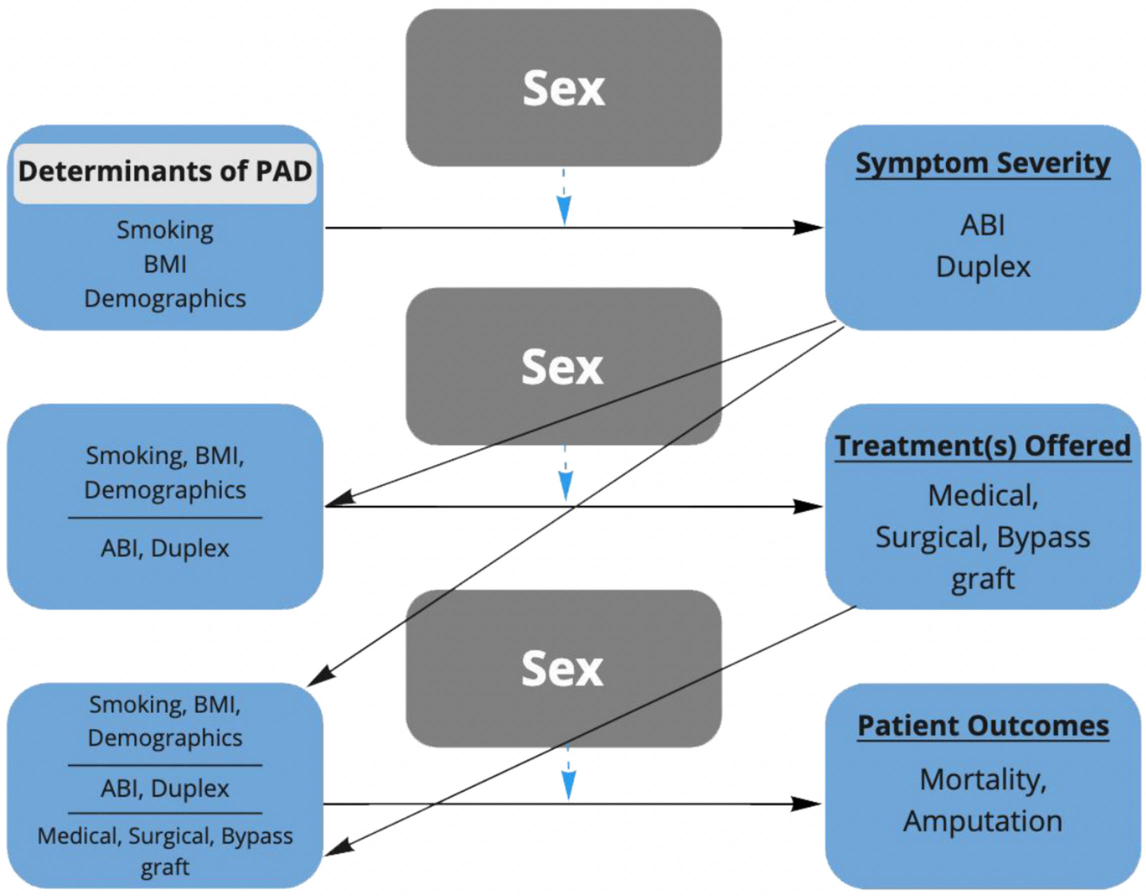

Figure. Conceptual Model. This recursive model illustrates the hypothesized moderating relationship of sex between select determinants of peripheral arterial disease (PAD) on symptom severity, select determinants of PAD and symptom severity on treatment(s) offered, select determinants of PAD and symptom severity, and treatment(s) offered on patient outcomes.

Results

Demographics and Determinants of PAD

All subjects included in the study had PAD. Univariate descriptive statistics were used to illustrate frequencies across demographic variables, including sex, subject age at the time of the study, age at initial diagnosis, race, marital status, and type of insurance coverage between men and women. Before analysis, categorical variables were converted to dummy variables to determine whether men and women differed in the determinants of PAD, therefore allowing the investigators to perform regression t-tests with dummy variables instead of a less robust nonparametric test.

The final cleaned and screened data set included 15,028 subjects, of whom 7545 (50.2%) were men and 7483 (49.8%) were women. Most subjects (84.4%) were White (n = 12,705), followed by African American (35%, n = 5235). Additionally, most (66%) were married (n = 9871). However, the number of widowed women (21.8%, n = 1631) far exceeded that of widowed men (7.5%, n = 566). **Table 1** summarizes the demographic characteristics of the subjects included in this sample. Likewise, **Table 2** summarizes the percentage of men and women, as well as mean differences between the groups for the selected determinants of PAD, which included smoking status and BMI.

Table 1. Demographic characteristics of the study population.

Demographic variable	Men (n = 7,545)	Women (n = 7,483)	Total (N = 15,028)
Age			
Mean (SD)	66 ± 10.67	65 ± 11.96	65.5 ± 11.37
Range	21-96	18-100	18-100
Age at diagnosis			
Mean (SD)	65 ± 10.67	64 ± 12.01	64.5 ± 11.36
Range	21-98	18-100	18-100
Race, n (%)*			
White	4602 (61)	4041 (54)	8643 (58)
Black or African American	2287 (30.3)	2948 (39.3)	5235 (35)
Asian	301 (3.8)	165 (2.2)	466 (3.1)
Hispanic	182 (2.4)	157 (2.1)	339 (2.3)
Pacific Islander/Native Hawaiian	98 (1.3)	97 (1.3)	195 (1.3)
American Indian/Alaskan Native	75 (~1)	75 (~1)	150 (<1)
Marital status, n (%)*			
Married	5583 (74)	4288 (57.3)	9871 (65.7)
Unmarried	1396 (18.5)	1564 (20.9)	2960 (19.6)
Widowed	566 (7.5)	1631 (21.8)	2197 (14.6)
Insurance, n (%)			
Medicaid	528 (7)	748 (10)	1275 (8.5)
Medicare	2716 (36)	2395 (32)	5111 (34)
Private	4150 (55)	4265 (57)	8415 (56)
Other**	151 (2)	76 (~1)	227 (1.5)

*n adjusted to sum 7545 and 7483, respectively, while minor differences in percentages not totaling 100% are attributed to rounding estimations. **Other includes Veteran (VA or Tricare), worker's compensation, cash (same-day pay rate), or professional courtesy. SD = standard deviation.

Table 2. Determinants of PAD for the study population.

Determinants of PAD	Men (n = 7,545)	Women (n = 7,483)	Total (N = 15,028)	*P* value
BMI				
Mean (SD)	29.36 ± 6.4	30.84 ± 7.7	–	<.001
Range	17-47.5	17-50	17-50	–
Smoking status, n (%)*				
Never smoked	1576 (20.9)	2843 (38)	4419 (29.4)	–
Current smoker	2323 (30.8)	2185 (29.2)	4508 (30)	–
Former smoker	3621 (48)	2439 (32.6)	6060 (40.3)	–
Unknown	25 (0.3)	16 (0.2)	41 (0.3)	–
Smoking status				
Never smoked – mean (SD)	20.9 ± 4.07	38 ± 4.9	–	<.001
Current smoker – mean (SD)	30.8 ± 4.6	29.2 ± 4.5	–	=.032
Former smoker – mean (SD)	48 ± 4.99	32.67 ± 4.69	–	<.001

*n adjusted to sum 7,545 and 7,483, respectively, while minor differences in percentages not totaling 100% are attributed to rounding estimations. PAD = peripheral arterial disease; BMI = body mass index; SD = standard deviation.

Degree of Symptom Severity (Stenosis)

The variable degree of symptom severity that describes the extent of arterial stenosis was assessed using subject ABI index values for right and left legs independently and CDF imaging scores. Despite hypothesizing that women would present with a greater degree of stenosis, there was no statistically significant difference for right leg ABI index values, t(15,026) = –0.07, *P*=.94, nor was there a statistically significant difference between sexes for left leg ABI index values, t(15,026) = –0.91, *P*=.36. It was also posited that women were less likely to have "normal" ABI values, regardless of extremity. However, results mirrored those findings related to ABI values, further refuting the original hypothesis.

There was a statistically significant difference between the 2 groups, where women were more likely than men to have a CFD imaging score of 0 or normal than men, t(15,026) = –19.19, *P*<.001. Conversely, 29% of men and 19% of women had a duplex score of 4, which corresponds to total occlusion of a vessel, indicating that men were more likely to present with the severest degree of stenosis and disease progression, t(15,026) = 14.23, *P*<.001, than their female counterparts (**Table 3**).

Table 3. Degree of symptom severity.

Degree of symptom severity	Men (n = 7,545)	Women (n = 7,483)	Total (N = 15,028)	*P* value
ABI value right leg				
Mean (SD)	1.02 ± .29	1.02 ± .24	–	.94
Range	0.01-2.54	19-3.69	–	–
ABI value left leg				
Mean (SD)	1.01 ± .29	1.02 ± .24	–	.36
Range	0.01 ± 2.56	0.01-3.85	–	–
Normal ABI right leg, n (%)				
	4225 (56)	4490 (60)	8715 (58)	<.001
Normal ABI left leg, n (%)				
	3999 (53)	4340 (58)	8339 (55)	<.001
Color-flow duplex imaging, n (%)				
0 (normal)	2112 (28%)	3142 (42)	5254 (35)	<.001
1 (30-49% occlusion)	792 (10.5)	726 (9.7)	1518 (10.1)	.106
2 (50-75% occlusion)	791 (10.2)	554 (7.4)	1345 (8.9)	<.001

This table provides information related to the degree of symptom severity by sex. *n adjusted to sum 7,545 and 7,483, respectively, while minor differences in percentages not totaling 100% are attributed to rounding estimations. ABI = ankle-brachial index; SD = standard deviation.

Initial Treatment Measures

Treatment measures were categorized as medical management, surgical procedure, or bypass graft, with bypass graft being the gold standard for revascularization measures regardless of sex.[8,18-19] Twenty-five percent of men and 25% of women received medical management following their initial diagnosis. In contrast, 8.9% of men and 6.6% of women underwent a surgical procedure. While no statistically significant difference was noted between men (M = 25, standard deviation [SD] = 4.3) and women (M = 25, SD = 4.3) for medical management, t(15,026) = –0.03, *P*=.977, there was a statistically significant difference between groups for those individuals who underwent a surgical procedure, in that men (M = 8.9, SD = 2.85) were more likely to undergo surgical repair than women (M = 6.6, SD = 2.5), t(15,026) = 5.35, *P*<.001. Additionally, men (M = 2.1, SD = 1.4) were twice as likely to receive a bypass graft than women (M = 1.2, SD = 1.1), t(15,026) = 1.66, *P*<.001 (**Table 4**).

Table 4. Initial treatment measures.

Initial types of treatment	Men (n = 7,545)	Women (n = 7,483)	Total (N = 15,028)	*P* value
Types of treatment, n (%)				
Medical	1886 (25)	1871 (25)	3757 (25)	–
Surgical	672 (8.9)	494 (6,6)	1166 (7.8)	–
Bypass graft	158 (2.1)	88 (1.2)	246 (1.6)	–
Types of treatment, mean (SD)				
Medical	25 (4.3)	25 (4.3)	–	.977
Surgical	8.9 (2.85)	6.6 (2.5)	–	<.001
Bypass graft	2.1 (1.4)	1.2 (1.1)		<.001

This table summarizes the percentage of men and women for each type of treatment and mean differences between groups for the treatment offered following an initial diagnosis of peripheral arterial disease. SD = standard deviation.

Patient Outcomes

Variables for patient outcomes were mortality and incidence of amputation analyzed for the 5-year time frame. Overall subject mortality rates were low, in that only 8.7% of men and 6.1% of women included in this sample reportedly died. Analysis suggests that men (M = 8.67, SD = 2.8) were more likely to die within this 5-year time frame than women (M = 6.08, SD = 0.24), t(15,026) = 6.07, *P*<.001. Moreover, being a current smoker was statistically significant, regardless of sex, with a 21% increased chance of death within 1 year following initial diagnosis.

The incidence of amputation was also low in the study population, whereas 0.01% of men and only 0.005% of women underwent amputation of an extremity. There was no statistically significant difference in amputation rates between men (M = .001, SD = 0.034) and women (M = 0.0005, SD = 0.023), t(15,026) = 1.37, *P*=.17. **Table 5** summarizes patient outcomes for subjects included in this sample.

Table 5. Patient outcomes.

Patient outcomes	Men (n = 7,545)	Women (n = 7,483)	Total (N = 15,028)	*P* value
Mortality, n (%)	656 (8.7)	456 (6.1)	1112 (7.4)	–
Mortality, mean (SD)	8.67 (2.8)	6.08 (0.24)	–	<.001
Amputation, n (%)	75 (0.01)	37 (0.005)	112 (0.007)	–
Amputation, mean (SD)	0.01 (0.03)	0.005 (0.02)	–	<.001

This table provides detailed information related to sex-based patient outcomes.SD = standard deviation.

The Moderating Effect of Sex

Multiple regression analysis examined the relationship between multiple predictor variables (PV), sex, and multiple dependent variables (DV). Using a recursive model, select determinants of PAD, the degree of symptom severity, and the initial treatment measures functioned as either PVs or DVs, depending on their sequencing within the model. Again, the final endpoint in the model was patient outcomes. The use of regression modeling assisted in determining the overall fit (variance explained) of the model and the relative contribution of each of the predictors to the total variance explained in the respective DVs. The significance level was set at .05, and SAS software was used for statistical analysis.

Based on the findings of previous research studies, the researcher hypothesized that sex would have a moderating effect on most of the variables of interest. However, the analysis revealed that female sex, in and of itself, did not moderate the effect of select determinants of PAD (smoking and BMI) on symptom severity as measured by ABI index values and CFD imaging scores when controlling for demographic characteristics and residential location using zip codes as a proxy.

In the initial results of the regression models with ABI values as the sole measure of stenosis when considering the impact of sex as a moderator on BMI and smoking, female sex did not influence the likelihood of receiving medical or surgical treatment. Conversely, female sex did decrease the chance of being treated with a bypass graft, whereas men had roughly twice the chance of receiving a bypass graft than women.

When CFD imaging scores were added to the models along with ABI values as measures of symptom severity, and when considering the impact of sex as a moderator on BMI and smoking, female sex also did not influence the likelihood of receiving medical or surgical treatment. However, unlike the model using ABI values as the sole measure of stenosis (as reported above), when CFD imaging scores were added, the probability of receiving a bypass graft was not influenced by female sex or other demographic characteristics. This difference is attributed to the significance of the variable CFD imaging score and its relevance as a more robust predictive test than ABI values alone to determine the degree of symptom severity and subsequent treatments offered for individuals with PAD.

The relationship between overall mortality rates and symptom severity was initially examined using ABI sum values only, then again including both ABI sum values and CFD imaging scores as measures of the degree of stenosis. In the initial analysis with ABI sum values alone, and after controlling for demographic characteristics (*P*=.10) and the fixed effect of zip codes (*P*=.05), female sex did decrease the risk of death within the 5-year data collection time frame. Conversely, female subjects who were current smokers lived shorter lives than all other subjects, regardless of sex, and died sooner than male smokers (*P*<.001). Likewise, individuals who underwent medical treatment were more likely to die than those who did not (*P*=.05), while individuals receiving a surgical intervention had the greatest risk of death in the basic model, the model when controlling for demographic characteristics, and the model with fixed effects for zip codes (*P*<.001).

When the variable CFD imaging score was added to the models, comparable results were found for age, female smokers, and individuals receiving a surgical intervention as in the models limited to ABI sum value as the sole measure of symptom severity. However, unlike the initial models, female sex, ABI sum value, and CDF imaging scores had no statistically significant impact on the length of life, which was an unexpected result. Outcome differences between the initial models and the subsequent models indicate that these previously significant effects were negated with the inclusion of the variable CFD imaging scores, making these results consistent with the other unique findings of this study. For example, in this population, women are not waiting for extended periods before being initially diagnosed with and seeking treatment for PAD. Moreover, despite some influence of female sex on these factors, providers at this specialty center refer to the overall clinical state of the patient as the primary driver for developing treatment plans, ultimately impacting patient outcomes.

Strengths and Limitations

There are several issues to consider when using large data sets for research purposes other than their primary intent. Before selecting a data set, investigators must ensure that the available data align with the purpose of the study. The integrity of the data is an additional concern, as it may be inaccurate, incomplete, or missing. For example, specific variables of interest needed to identify predictive factors reported in the literature may be unavailable or collected in an unusual format. Finally, secondary data sets lack standardization and frequently require the recoding of variables, which is labor intensive and may be cost or time prohibitive.[19]

Another limitation of this study was the use of purposive sampling with a strong regional focus, which limits the generalizability of the findings. Further, while CIS provides comprehensive cardiovascular care in 22 clinics across southwest Louisiana, information from all clinics was combined into one data set, and separate analysis for individual patients at each clinic was not done, making the setting for the study a single-center site.

Strengths of this study include a large sample size, which sufficiently powered the study and allowed the use of robust statistical analysis methods. No unplanned post hoc analyses were conducted when examining subsets of the original sample. Additionally, of those variables of interest included in the dataset, only a small amount of data was missing.

Conclusions

While some statistically significant sex-based differences were found, not all were clinically relevant. Conversely, some sex-based differences were noted that were not statistically significant but were believed to be clinically meaningful. The most relevant finding of this study was that when CFD imaging scores were added to the models as a measure of symptom severity, its inclusion frequently negated any interaction or moderating effect of sex. While ABI is the most common noninvasive method used to diagnose PAD, triggering specialist referral, the addition of CFD imaging scores better informed treatment decisions. It was an essential driving force for the type of initial treatment measures offered and subsequent patient outcomes, suggesting that CIS clinicians are first and foremost attending to the overall clinical state of the patient and using the most robust diagnostic tools to determine a treatment plan mitigating adverse outcomes. Patients with PAD seen at this high-quality specialty center in southwest Louisiana receive appropriate interventions for PAD sooner than patients with similar disease in other parts of the country, regardless of sex. Future work could focus on replicating this study in a data set associated with a traditional clinic, a nonspecialty center, or other geographic areas to see if sex-based differences influence the diagnosis, treatment, and outcomes of individuals with PAD.■

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