A MIXED METHODS STUDY OF THE SYMPTOM EXPERIENCE FOLLOWING ENDOVASCULAR TREATMENT FOR LOWER EXTREMITY PERIPHERAL ARTERIAL DISEASE

by

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DEDICATION

I dedicate this dissertation to my husband, Rick, my children, Emma and Tommy, my sister, Aleisha, and my parents, Tom and Diane Greenhaw. Without your consistent, support, and encouragement during the pursuit of my PhD degree, this achievement would not have been possible. Rick, when I was feeling down you stood beside me and lifted my spirits with your words of support and gestures of love. Emma, I will always remember you telling me how proud you were of me with each milestone. Tommy, I appreciate your understanding with my limited schedule and that you still managed to tell me, "you've got this." Dad, I will forever be grateful for you pushing me to be better, asking for frequent updates with my progress, and offering positive thoughts and advice. Last, but not least, Mom, I am so thankful for such a positive, hard-working role model to show me how to be a strong and independent woman. Your perseverance, dedication, and work ethic are just a few of the reasons I admire and love you.

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ABSTRACT

SERENA GREENHAW GRAMLING
A MIXED METHODS STUDY OF THE SYMPTOM EXPERIENCE FOLLOWING ENDOVASCULAR TREATMENT FOR LOWER EXTREMITY PERIPHERAL ARTERIAL DISEASE
Under the direction of TAMMY BARBÉ, PhD, RN

Peripheral arterial disease (PAD) is one of the most understudied and undertreated diseases affecting three to ten percent of the general population. Patients with lower extremity PAD must manage multiple symptoms including pain in the hips, thighs, and calves during rest and physical activity. However, evidence is limited about patients' experience, especially following treatment. The purpose of this mixed methods study was to explore the symptom experience of individuals with peripheral arterial disease following endovascular treatment including perceptions of treatment benefit and concerns.

Using a convergent parallel mixed methods study design, 65 participants (mean age = 56.9 years, 73.8% female, 95.4% white) participated in a web-based survey. Quantitative data were collected utilizing six questionnaires: a researcher developed demographic and clinical history questionnaire, the Patient Health Questionnaire 9 (PHQ-9), the Walking Impairment Questionnaire (WIQ), the San Diego Claudication

Questionnaire (SDCQ), the VascuQOL-25, and the Peripheral Artery Questionnaire (PAQ). Qualitative data were collected using open-ended questions within the web-based survey.

The most commonly reported symptom by participants was pain in both legs while walking. Greater age was significantly associated with less symptoms, less pain, being more active, and being more social. Men reported better physical functioning, walking ability, and overall quality of life compared to women. Participants with PHQ-9 scores indicative of depression reported greater difficulty controlling their symptoms. No significant relationships were found between having a diagnosis of diabetes and symptom experience or quality of life.

Qualitative data analysis revealed four themes. One theme concerning benefits of treatment was described as *continuum of benefit.* The three themes related to concerns with treatment were described as *outcome, process, and coping.* Qualitative data supported the quantitative results related to symptom experience, gender, and depression. Qualitative data diverged with the quantitative results related to age as within the qualitative data younger participants reported more positive treatment outcomes than older participants. The findings from this study have the potential to provide better insight into the experiences of individuals with PAD and guide interventions for improved care and outcomes.

CHAPTER 1

INTRODUCTION TO THE STUDY

Peripheral arterial disease (PAD) is an atherosclerotic vascular disease affecting three to ten percent of the general population with those estimates increasing to 15% to 20% in those aged 70 years and older (Siracuse et al., 2016). The peripheral arteries become narrowed and impede blood flow causing ischemia, in the lower extremities most commonly, but these pathological changes can also occur in the abdomen, upper extremities, and brain. Symptoms may include pain or muscle cramping in the hips, thighs, or calves, especially during physical activity. The pain, known as intermittent claudication, consists of leg discomfort during exertion as the result of lack of arterial blood flow, which typically subsides after a few minutes of rest (Agrawal & Eberhardt, 2015). As the disease advances, patients may also experience resting leg pain, delayed wound healing, ulcerations, a decrease in color and temperature of the affected limb, and possibly gangrene (Kevil, Bir, Pattillo, & Akkus, 2013; Turns, 2011).

A compilation of practice guidelines for managing PAD was created in 2005 (Hirsch et al., 2006) by the American College of Cardiology Foundation (ACC) and American Heart Association (AHA) and later revised in 2011 to provide a single reference resource. These guidelines provide recommendations for obtaining vascular history and physical exam, utilizing diagnostic methods, and initiating treatment for PAD. Treatment may be medical, endovascular, or surgical depending on severity of symptoms (Rose, 2015). Research has shown physical therapy to have little to no benefit

due to a majority of patients having atypical symptoms until the disease is well advanced (Vakili et al., 2012), especially in geographical areas where treatment options are limited. Many patients disregard symptoms and assume they are related to advanced age, joint pain, neuropathy, or arthritis when the pain is actually originating from ischemic muscles (Rose, 2015). The priority in managing PAD is reducing gangrene / amputation, cardiovascular complications, and death (Rose, 2015). Medical treatment may include increased activity, dietary changes, pharmacotherapy, smoking cessation, and supervised exercise programs. Endovascular treatment options consist of balloon angioplasty or stenting of the affected arteries. Surgical procedures may include lower extremity bypass or amputation (Jaff et al., 2015).

Statement of the Problem

Peripheral arterial disease is one of the most understudied and undertreated diseases, especially in women (Teodorescu, Vavra, & Kibbe, 2013). The prevalence of PAD continues to escalate due to increasing numbers of patients with diabetes and a rise in the elderly population (Adams et al., 2016). The disorder has an associated cost of $50,110 per patient per year (Jaff, Cahill, Yu, Bimbaum, & Engelhart, 2010). Those with PAD are two to three times more likely to have a cerebrovascular accident (CVA) and three times more likely to have a myocardial infarction (MI) than those without PAD (Kohlman-Trigoboff, 2013). The incidence of PAD cases in 2001 was eight to twelve million (Hirsch et al., 2001), whereas in 2010 the number had soared to eighteen million (Schiavetta et al., 2012). Although it can be life-threatening, PAD can be managed and potentially reversed with appropriate medical care. Previously, PAD was thought to occur more frequently in men than women; however, more recent data suggest the

incidence between genders is possibly higher in women (Barochiner, Aparicio, & Waisman, 2014). Hirsch et al. (2012) determined evidence supporting gender and age specific prevalence of PAD to be unclear and recommended further population-based studies.

According to Flu, Tamsma, Lindeman, Hamming, and Lardenoye (2010), lack of utilization of treatment can be patient-related, physician-related, or healthcare system-related. Patients traditionally do not seek treatment for PAD because they do not realize they are experiencing a vascular problem. Patients should be involved in their own care, have regular visits with a provider and receive medical education from healthcare providers to effectively manage symptoms (Renard et al., 2015).

Patients typically do not seek treatment until they become symptomatic. Once symptomatic, the responsibility of managing symptoms and preventing negative outcomes can be burdensome for patients and families. Activities of daily life, as well as overall quality of life, can be severely disrupted if symptoms are mismanaged or uncontrolled (Lee & Miaskowski, 2016). Healthcare providers struggle with developing strategies to manage symptoms in individualized settings due to the lack of tested models of symptom management. A clear understanding of the symptom experience of patients with lower extremity PAD has the potential to inform clinical practice and promote quality of life. However, the evidence base to support symptom management is lacking with PAD.

Nurses remain at the forefront to assist patients and their families with PAD symptom management. Nursing research is needed to explicate the symptom experience of persons with lower extremity PAD so that evidence-based interventions to promote

symptom management can be further developed and tested. Of particular concern with symptom management are patients with PAD experiencing endovascular treatment with percutaneous balloon angioplasty or stenting. Few studies have examined patients during the clinical course of endovascular treatment for lower extremity PAD. Furthermore, little is known about patients' perceptions of benefits of therapy.

According to Van Zitteren et al. (2015), eligibility criteria remains ambiguous for patients undergoing endovascular treatment for lower extremity PAD. However, results suggested patients who had a poorer pre-procedural health status had the most improvement post-procedure with fewer symptoms of claudication (Van Zitteren et al., 2015). Other post procedural benefits have been identified as improved walking abilities, increased muscle strength / endurance, and improved cardiac function (Gardner & Poehlman, 1995; Hiatt, Wolfel, Meier, & Regensteiner, 1994; Pollock et al., 2000). However, these data are not recent. Due to the limited data currently available related to the symptom experience and perceived treatment benefit of those undergoing endovascular treatment for lower extremity PAD, a study of the symptom experience of patients undergoing endovascular treatment for PAD has the potential to provide better insight into the experiences of these patients for healthcare providers and guide interventions for improved care and outcomes.

Purpose of the Study

The purpose of this mixed methods study was to explore the symptom experience of patients with peripheral arterial disease following endovascular treatment including perceptions of treatment benefit and concerns.

Research Questions

The following research questions were proposed:

Quantitative Research Questions:

1. What is the symptom experience (leg pain / discomfort, other symptoms, emotional response to symptoms) of patients following endovascular treatment for lower extremity PAD.
2. Are person factors (age, gender), health and illness factors (diabetes, depression), and symptom experience (leg pain, discomfort, other symptoms, emotional response to symptoms) correlates of quality of life following endovascular treatment for lower extremity PAD?

Qualitative Research Questions:

3. What are patients' perceptions of the benefits of endovascular treatment for lower extremity PAD?
4. What are patients' concerns following endovascular treatment for lower extremity PAD?

Mixed Methods Research Question:

5. Do the quantitative data and qualitative data converge around the symptom experience of patients with PAD?

Conceptual Framework

Barsevick, Whitmer, Nail, Beck, and Dudley (2006) explained there is a paradigmatic evolution occurring in the area of symptom management research. Whereas previous research focused on evaluating individualized symptoms in a cross-sectional manner (Miaskowski, Dodd, & Lee, 2004), other studies incorporated plural paradigms

using knowledge from basic science, behavioral science, and clinical experiences (Weaver & Schnoll, 2002). Recent research has examined concurrent symptoms as well as the meanings of the symptoms such as changes over time, effectiveness of interventions, and measurement of nurse-sensitive patient outcomes (Barsevick et al. (2006). The conceptual framework for this study was the theory of symptom management which is also referred to as symptom management theory (SMT). It is a middle-range theory depicting symptom management as a multidimensional process. Leventhal, Meyer, and Nerenz (1980) further described a symptom as being a concrete representation of a disease process experienced and processed cognitively by an individual. Humphreys et al. (2014) described a symptom as a subjective experience reflecting changes in the biopsychosocial functioning, sensations, or cognition of an individual.

Physical, mental, and social functioning may be disrupted while symptomatic and symptoms may be the first clue for an individual that something is wrong. It is important for clinicians and patients to understand symptoms are not always produced from an illness independently, but can also be generated by medical and / or pharmacologic treatments as well. The goal in managing a symptom or cluster of symptoms may not necessarily be to eradicate the symptom(s) but possibly to minimize effects of the symptom(s) (Humphreys et al., 2014).

SMT resulted from an evolutionary process which began as the University of California at San Francisco (UCSF) symptom management model (Larson et al., 1994). It was proposed by nursing faculty with a broad scope of programs of research at UCSF as an organizational framework to assist faculty with collaboration in clinical practice and

improve symptom research (Humphreys et al., 2014). The model was influenced by other nursing models such as Orem's self-care model (1971, 1980, 1985) and Sorofman, Tripp-Reimer, Lauer, and Martin's model of symptoms of self-care (1990) as well as other anthropological, sociological, and psychological models along the way (Humphreys et al., 2014). After further testing and discussion, the model was revised in 2001 and the relationships among the concepts of symptom management were modified to include the influence of person, environment, and health (Dodd et al., 2001). In 2008, the concept of adherence was added, which is reflected externally to the dimensions of symptom management. The model was then renamed Symptom Management Theory. The SMT has become an important foundational framework for nursing research, general nursing practice, and nursing education (Humphreys et al., 2008). Figure 1 depicts a visual representation of the SMT.

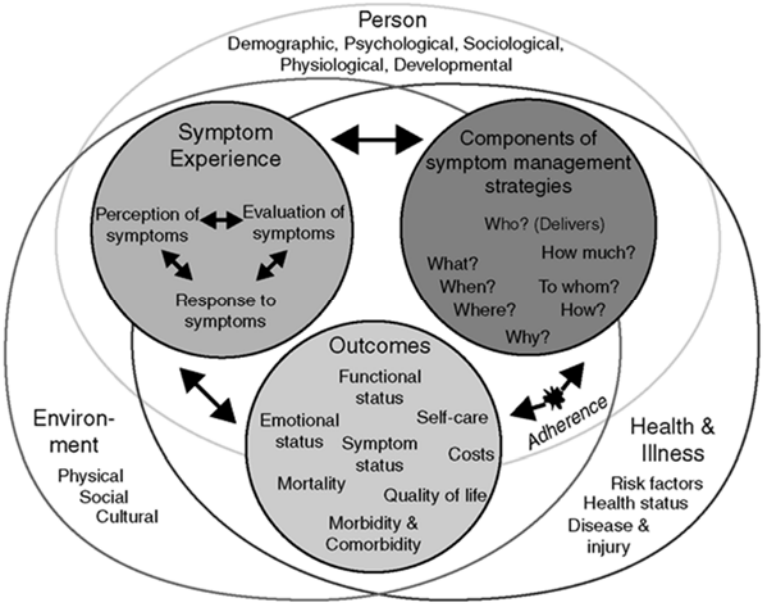

Figure 1. Symptom Management Model.

According to Dodd et al. (2001), there are six assumptions in the SMT which reflect the relationships between the nature of symptoms and the focus of symptom management strategies within the model. First, analysis of symptoms is based on a self-report of an individual's perception of the symptom. Second, individuals do not actively have to be experiencing a symptom for the model to apply. They may be at risk for developing a particular symptom based on their surrounding environment which allows healthcare providers an opportunity to intervene and potentially prevent symptoms from occurring. Third, a parent or caregiver may be in a position to interpret symptoms for nonverbal patients and that is acceptable for intervention purposes. Fourth, all symptoms creating discomfort or disruption of life must be managed. Fifth, management of symptoms may be directed at an individual or a group. The sixth assumption is symptom management is an evolutionary process and can be influenced by individual outcomes within the domains of person, health, illness, or environment (Dodd et al., 2001).

Patients' symptoms should be thoroughly assessed to understand what they are experiencing. For example, a person might present for treatment with leg pain. If improperly assessed, the patient could be misdiagnosed. Symptoms of PAD may be described as sharp, stabbing, throbbing, a feeling of fullness, or it might be that only one small area of the leg is uncomfortable. Assessment within the context of the theory would involve determining if the pain is constant or intermittent, how distressing the symptoms are, and whether or not they are affecting life activities. In some cases, multiple symptoms may be occurring simultaneously, thus creating a synergistic effect (Humphreys et al., 2014).

There are three fundamental simultaneously interacting components of SMT / Symptom Management Model (SMM) including symptom experience, symptom management strategies, and symptom status outcomes. These components are embedded within the three nursing science domains of person, environment, and health / illness (Humphreys et al., 2014). Symptom experience occurs in the beginning of the symptom management and involves an individual's perception, evaluation, and response to the symptom when it occurs.

Symptom management, the second component of the SMM, is associated with investigating the "what where, why, how much, to whom, and how" (Dodd et al., 2001, p. 673) in order to determine the appropriate intervention strategies and "avert, delay, or minimize the symptom experience" (Humphreys et al., 2008, p. 147). When this component is implemented, multiple strategies may be required to accomplish set goals. Adherence is an important part of symptom management and is defined as "whether the intended recipient of the strategy actually receives or uses the strategy prescribed" (Dodd et al., 2001, p. 674). Preventing nonadherence is an important factor in successful symptom management and can be promoted by ensuring interventions are not overly demanding in addition to encouraging appropriate and timely application of interventions (Linder, 2010).

Along with assessment, Humphreys et al. (2014) suggests healthcare providers should develop ways to manage symptoms such as further testing, pharmacological planning, wound care, and collaboration with other disciplines such as anthropology, sociology, and psychology. The objective in symptom management is to prevent, reduce, or delay unwelcomed symptoms (Humphreys et al., 2014). Self-management strategies

may also be effective as the person learns to cope with his or her illness (Landers, McCarthy, & Savage, 2011; Zimmerman et al., 2011). However, self-management strategies are challenging to develop without an evidence base.

When evaluating symptom status outcomes in response to interventions, the implementation of a strategy is assessed by examining clear and measureable outcomes. The third component, outcomes, occurs as a result of the symptom experience or symptom management. The outcomes may be related to symptom status, functional status, emotional status, self-care, costs, quality of life, morbidity, comorbidity, and mortality (Dodd et al., 2001).

For example, after an intervention is implemented, it would be determined if symptoms have been improved or eliminated or no change has occurred. Improvement in symptoms can lead to better quality of life for an individual by decreasing stress, improving mental and physical function, and decreasing healthcare cost (Humphreys et al., 2014).

Although SMT is limited to the phenomenon of symptom management, it is easily applicable to a variety of illness states where individuals experience symptoms, including PAD. This research study involved describing symptom experiences, exploring quality of life, and investigating perceptions of treatment benefit for patients following endovascular treatment for lower extremity PAD. According to Linder (2010), the perception of an individual's symptoms, may be different from another person's perception. Healthcare providers must individually evaluate patients' symptoms as well as the response to those symptoms.

The next step would be to determine how the symptoms are going to be managed. For example, the patient might begin a walking regimen to develop collateral circulation, hang the legs in a dependent position, or stop activity when pain ensues. The role of the provider is to determine who is going to be managed, who is going to do the managing, how the PAD symptoms are managed, what the provider and patient are going to do, how much care is needed, when it will occur, where it will occur, and why the patient needs to be managed. Successful outcomes are reflected in the patients' motivation to adhere to recommended strategies and is influenced by the extent to which the clinician understands the patients' experiences and collaborates with them about the treatment plan. Consequently, effective symptom management requires an evidence base around how PAD patients perceive their symptoms following treatment. Those who do not adhere to symptom management strategies may be forced into an unpleasant outcome with a lifelong handicap. Outcomes relevant for PAD that have been associated with the SMT framework include functional status- especially walking, quality of life, and morbidity (Linder, 2010). Perception of benefit, as well as concern about symptoms, depend on the symptom experience, symptom management strategies, and quality of life / other outcomes exhibited following endovascular treatment. Environmental factors, such as a person's surroundings, conditions, or geographical area may also affect physical, social, and cultural aspects of the symptom experience of PAD.

Significance of the Study

This study was conducted to address a critical gap in nursing literature related to the symptom experience of patients with lower extremity PAD who have undergone endovascular treatment. An empirically tested framework (SMT) was used to guide the

exploration the symptom experience of patients. The outcome of interest was health-related quality of life in multiple domains. The findings provided an increased understanding of the symptom experience of patients with lower extremity PAD and their quality of life after treatment. Treatment concerns and benefits were explored as linkages to quality of life. The mixed methods design enabled the researcher to gain an understanding of the symptom experience from both a quantitative and qualitative perspective which has the potential to make an important contribution to the literature.

Definition of Terms

The following terms were utilized in this study and are conceptually defined as follows:

Ankle-brachial index (ABI) - a non-invasive exam performed using a hand-held Doppler device to obtain systolic blood pressures in the dorsalis pedis or posterior tibial arteries of each leg and the systolic blood pressures in the brachial arteries of each arm. Once the pressures are obtained, they are recorded as a ratio which reflects the severity of PAD (Kevil et al., 2013).

Collateral circulation - An alternative source of blood supply re-routed to the heart due to an ischemic event which has caused an obstruction (Seiler, 2003)

Concern - A situation warranting a patient to be troubled, care about, or cause distress. (Merriam-Webster, 2017)

Endovascular treatment - Minimally invasive techniques such as balloon angioplasty, stenting, and artherectomy used to revascularize patients with lower extremity PAD experiencing critical limb ischemia (Siracuse et al., 2016)

Intermittent claudication - Manifestations of PAD consisting of leg pain during exertion as the result of lack of blood flow to a particular area of the body typically subsiding after a few minutes of rest (Agrawal & Eberhardt, 2015).

Leg pain - Symptoms associated with claudication such as pain, cramping, numbness, generalized discomfort in the lower leg, calves, thighs, and / or buttocks.

Open vascular surgery (also known as "Bypass") - Surgical procedures, known as endarterectomy or arterial bypass, or both, where blocked arteries are revascularized (Siracuse et al., 2016).

Peripheral arterial disease - Disorder caused from atherosclerotic accumulation in the arteries which can block blood flow to critical areas of the body when plaque accumulates and forms a lesion (Rose, 2015).

Quality of life - A multidimensional concept often involving physical, social, psychological, and spiritual factors (Haas, 1999); "an individual's perception of their position in life in the context of the culture and value systems in which they live, and in relation to their goals, expectations, standards and concerns. It is a broad ranging concept, incorporating in a complex way a person's beliefs and relationship to salient features in the environment" (WHOQOL Group, 1998, p. 43).

Symptom - A concrete representation of a disease process experienced and processed cognitively by an individual (Leventhal et al. 1980). For purposes of this study, a symptom was defined as something abnormal patients are experiencing, such as pain, numbness, etc., as it is related to PAD and endovascular procedures they have experienced.

Symptom experience - Involves individual's perception, evaluation, and response to the symptom when it occurs (Dodd et al., 2001).

Symptom occurrence - The cognitive component of symptom experience which can be measured on a scales of frequency and / or severity (Ordin, Karayurt, & Cilengiroglu, 2013).

Symptom management - Investigating the "what where, why, how much, to whom, and how" (Dodd et al., 2001, p. 673) in order to determine the appropriate intervention strategies and "avert, delay, or minimize the symptom experience" (Humphreys et al., 2008, p. 147).

Treatment benefit - A condition demonstrated by evidence that the treatment has a positive impact on a meaningful concept of interest. Examples include how long a patient survives or how a patient feels or functions in daily life (Papadopoulos, n.d.).

Summary

Peripheral arterial disease is one of the most understudied and undertreated diseases globally (Teodorescu et al., 2013). The purpose of the study and research questions were presented in this chapter along with a conceptual framework to guide the study. The significance of the study was described and a list of defined terms associated with the proposed research study was also included. The findings of this study provided an increased understanding of symptoms experienced by patients undergoing endovascular treatment for lower extremity PAD.

CHAPTER 2

REVIEW OF RELATED LITERATURE

This chapter will provide a review of educational, nursing, and medical literature related to the symptom experience of patients undergoing endovascular treatment for lower extremity PAD. The Symptom Management Theory (SMT) described in chapter 1 will provide the overarching structure for chapter two. Initially, the symptom experience of persons with PAD will be described. The second section will discuss risk factors for PAD, prevalence, and associated effects. The third section will provide a review of SMT where studies will be cited in order to show its relevance for the study. The fourth section will discuss symptom management techniques utilized by patients undergoing endovascular treatment for PAD, followed by a review of treatment outcomes. Finally, the fifth section will present a review of gaps in current literature along with recommendations for future studies concerning PAD.

Synthesis of Literature

Peripheral arterial disease is an alarming disease that can restrict or prevent circulation to the brain, limbs, and other organs potentially causing irreversible damage. According to Schorr, Peden-McAlpine, Treat-Jacobson, and Lindquist (2015), the most common recognized symptom of lower extremity PAD is claudication. More specifically, patients complain of aching, cramping, or a tired feeling in the calves or thighs as a direct result of ischemia to the muscles. Other considerations affecting symptoms include age, gender, and ethnicity. Along with claudication, PAD patients can

experience atypical symptoms such as burning in the quadriceps. Schorr et al. (2015) interviewed PAD patients about symptoms who reported cramping, aching, burning, and fatigue in the calves, thighs, or buttocks. These typical and atypical symptoms greatly impact quality of life for individuals with lower extremity PAD (Schorr et al., 2015).

Claudication severity has been established by using one of two classification schemes known as Rutherford-Becker or Fontaine. The Rutherford-Becker classification has a 0 to 6 scale with classifications described as asymptomatic (0), mild claudication (1), moderate claudication (2), severe claudication (3), ischemic rest pain (4), minor tissue loss (5), and major tissue loss (6). The Fontaine classification is graded from I to IV where patients' status is described as being asymptomatic (I), mild claudication (IIa), moderate to severe claudication (IIb), ischemic rest pain (III), and ulceration or gangrene (IV) (Rutherford et al., 1997).

Data surrounding symptom experiences of endovascular treatment strategies for lower extremity PAD are sparse. According to Je et al. (2015), patients reported improved symptoms following revascularization but the results focused on improved quality of life and ankle brachial index (ABI) rather than specific symptoms. Patients who are unsuccessfully treated with medical management may be candidates for minimally invasive endovascular treatment options. According to Klein and Ross (2016), endovascular treatment has proven to be effective in treating lifestyle limiting claudication, critical limb ischemia, and acute limb ischemia. The most common endovascular procedures are balloon angioplasty and stenting. Though advanced disease and longer lesions may be factors in arterial stenosis, newer technologies such as drug coated balloons, drug-eluting stents, and bioabsorbable stents are expected to

significantly decrease future cases of restenosis. Currently there are no standardized treatment protocols for endovascular therapy, therefore, treatment is guided through evidence based practice and expert consensus (Klein & Ross, 2016).

The most common vascular areas treated with endovascular therapy are the aorto-iliac vasculature, common femoral artery, and femoropopliteal segment (Klein & Ross, 2016). Aorto-iliac intervention is associated with lower morbidity / mortality and is the primary choice for revascularization. The common femoral artery has traditionally been treated with an open surgical approach, but more recently interventionists have used stenting with great success (Klein & Ross, 2016). However, this area has an approximately 28% risk of restenosis within one year following treatment (Bonvini et al., 2011). Due to the twisting nature and long calcified segments of the femoropopliteal segment, older studies have reported suboptimal outcomes with recurrent re-stenosis (Dorrucci, 2004; Gray & Olin, 1997; Laird, 2006). However, more recent research suggests success rates greater than 90% with an antegrade approach and near 100% for retrograde techniques and supports endovascular treatment as first-line treatment for revascularization (Bausback et al., 2011; Schmidt et al., 2012). Antiplatelet drug therapy is also prescribed to help promote vessel patency and reduce risk of limb ischemia.

Historical Perspective

Peripheral vascular disease is not a recent phenomenon. Evidence from Egyptian mummies documented histological changes in the calf muscles which are identical to patients with peripheral arterial disease in the current era (Sandison, 1962). The concept of tissue damage related to ischemic changes was later discovered in the early seventeenth century by William Harvey (Harvey, 1628; Harvey, 1649). Gangrene was

the first symptom to be associated with peripheral arterial disease in 1771 (Quesnay, 1771). Historically, French physicians have been very progressive in cardiovascular research. Bouley (1831) introduced the concept of intermittent claudication by describing its effects in a horse. Later, Brodie (1846) described the concept as it applied in the human body. Although intermittent claudication was well documented and recognized prior to World War II, (Andre-Thomas & Levy-Valensin, 1918; Comroe, 1923) it was thought to be caused by arterial spasm (Zak, 1921). Sir Thomas Lewis refuted these claims by elucidating the concept of dilatation of arterioles during exercise with and without atherosclerosis within the vessels and providing an explanation for pain symptoms (Lewis, Pickering, & Rothscild, 1931).

Tonscillography, measurement of arterial pressure wave at different levels in the leg, was one of the first methods used to determine the presence of intermittent claudication (Ejrup, 1948). The effectiveness of this procedure was confirmed by McDonald and Semple (1952) when they replicated the measurements with similar equipment. More unreliable methods have also been used with the Dinamap machine (Adiseshiah, Cross, & Belscham, 1987) due to the inability to record measurement of blood pressures less than 50 mm of Hg (Shearman & Sims, 1988). A more invasive technique with the use of clearance of radioactive isotopes to measure limb blood flow was introduced by Kety (1948), although this method is not widely accepted by the medical community. Other procedures such as arteriography with iodine salts and contrast medium, ultrasound and Doppler flow measurement, and the ankle / brachial pressure ratio are successful techniques used for detecting PAD (Cheatle, Sarin, Coleridge-Smith, & Scurr, 1991).

Mohler (2012), Rooke et al. (2011), and Mahameed (2009) identified advanced age, diabetes, hypertension, hyperlipidemia, and current smoking, or history of smoking as significant risk factors for PAD. Although age, history of smoking, history of cardiovascular disease, and history of stroke are not modifiable, smoking can be eliminated and obesity, hyperlipidemia, and hypertension can be managed through diet, exercise, and pharmacological regimens. Those with diabetes, hyperlipidemia, and hypertension should maintain a healthy target blood glucose range, cholesterol levels, and blood pressure. A risk factor currently disputed, but associated with PAD, is male gender. Warren (2013) reported males were more likely to experience PAD, however, Barochiner et al. (2014) did not support the claim stating many studies had shown women to have an equal or higher incidence of developing PAD.

Symptom Experience of PAD / Endovascular Treatment

Few studies have formally examined the symptom experience of patients with PAD, as the condition involves extended periods when the patient is asymptomatic. Once symptoms emerge, PAD has typically progressed to an advanced stage. The main symptom experience with lower extremity PAD is pain in the legs with symptoms of claudication (cramping in the legs or hips), ischemic rest pain, and / or presence of non-healing wounds. PAD also affects a person psychologically and socially in that he or she may develop limited mobility resulting in social isolation and dependency. It is important to address the patient needs with a comprehensive approach to develop an appropriate treatment plan.

From a healthcare perspective, patients with PAD experiencing intermittent claudication present with calf, thigh, buttock, or leg pain upon exertion. Hirsch et al.

(2001) and McDermott et al. (2001) both found only 2.5% to 33% of patients reported classic symptoms of intermittent claudication associated with lower extremity PAD. More recent data indicate patients reported symptoms related to heavy feelings in the legs, loss of power, weakness, and numbness (Klein & Ross, 2016). Of those patients who are symptomatic, symptoms typically subside with rest. This encourages a cycle of deconditioning as patients respond to symptoms by decreasing physical activity. Patients may report a decrease in frequency of symptoms over time because they have declining functional status with less mobility rather than slowing of the progression of PAD (McDermott et al., 2004).

According to Je et al. (2015), the goal in endovascular treatment of PAD is to improve symptoms, functional status, and quality of life by reducing or alleviating symptoms. Je et al. (2015), quantified health status improvement and evaluated the Peripheral Artery Questionnaire, a PAD-specific quality of life measure, and the ABI. One hundred and forty-nine patients were recruited for assessment of symptoms before and three months following revascularization for PAD. One hundred underwent endovascular treatment and 49 underwent bypass surgery. No major complications occurred with the exception of three patients with access site hematomas. The participants' main concerns were symptom relief and improvement in daily functioning. Results indicated improvement in all six domains of the PAQ (symptoms, symptom stability, physical limitation, treatment satisfaction, social functioning, and quality of life) with the most significant improvement in the symptoms category and the least improvement in the treatment satisfaction category. Although overall PAQ summary scores for endovascular treatment and bypass surgery were similar, those undergoing

endovascular treatment had significantly greater improvement in the category of social limitation compared to those following endovascular treatment.

Wann-Hansson and Wennick (2016) used a qualitative study design with purposive sampling and focus group methodology to learn about participants' experiences following endovascular treatment in the past six months for PAD. Twenty-one participants were included and seven focus groups were created for interview purposes. Some participants described feelings of uncertainty about the future or expressed guilt about smoking or their lifestyle. Others reported insufficient knowledge about PAD and attributed their leg symptoms / pain to growing old. One person feared she might not be able to walk even after the procedure. Upon returning home after the procedure, some felt a sense of relief followed by a period of uncertainty about what to do next. Participants also reported having a sense of relief after being cured, which indicated he or she was misinformed about the procedure results and the chronic and progressive nature of PAD (Wann-Hansson & Wennick, 2016).

Although there are multiple studies involving PAD, there is a gap in the literature concerning the symptom experience of patients undergoing endovascular treatment. Pettersson and Bergbom, (2010) conducted research involving patients undergoing open repair and endovascular treatment for aortic aneurysm repair. Gadamer's hermeneutic approach was used in a qualitative study of 20 patients. The researcher approached patients during the admission process prior to surgery and asked them if they were willing to be interviewed one month after surgery about their experiences. The first 20 patients approached accepted the invitation. Patients were asked to describe their experiences and answer questions concerning quality of life. Three themes emerged for

endovascular patients in the study including an inability to come to terms with a life-threatening condition, being granted a new lease on life, and a sense of living on borrowed time. Some patients undergoing endovascular treatment felt insecure while others felt a sense of gratitude and security. Pain control was another concern. Patients undergoing open repair required more pain control and longer hospital stays than those undergoing endovascular treatment. Only 15% of patients considered endovascular treatment to be a difficult experience as compared to 50% of patients with open repairs. Patients undergoing endovascular treatment described the pre-procedural psychosocial experience as "waiting under the threat of death", "living with the awareness that the illness is life threatening", and "existing in an unreal world" (Pettersson & Bergbom, 2010, p. 5). Waiting for the procedure resulted in questions surrounding rupture of the aneurysm and death. Some described it as waiting for a death sentence and time passing by slowly. Post-procedure, patients described the psychosocial experience as feeling "grateful", "lucky", "calm feeling", and "loving life" (Pettersson & Bergbom, 2010, p. 5). The physical experience post-procedure was described by some as little to no pain while others were impressed with the small scar left. Follow up radiologic procedures were seen as positive experiences filled with confidence that health care workers were keeping an eye on them. (Pettersson & Bergbom, 2010).

Corriere et al. (2015) explored the perception of involvement with decision making for patients undergoing vascular procedures. A sample size of 81 participants were recruited from an outpatient clinic and contacted by phone or in person. A survey questionnaire consisting of multiple choice items, Likert scales, and open-ended questions was completed by participants one to six months following a vascular

procedure. Some of the patients with PAD described their experience as being confusing or overwhelming and reported having little understanding of their diagnosis. However, the majority of the sample actively participated in their care, were well informed, did not feel overwhelmed, and had interactive discussions with their providers. Forty six percent of patients indicated their first treatment was successful. Thirty six percent of patients indicated a second treatment was successful. Only 16% of patients with PAD described their vascular treatment as being unsuccessful (Corriere et al., 2015).

Zafar, Harris, Murphy, and Machan (2011) conducted a cross-sectional study at a free standing outpatient vascular and interventional radiology clinic to determine patients' heuristics concerning treatment for PAD. The population consisted of patients diagnosed with intermittent claudication presenting for invasive vascular treatment. There were 20 participants with a median age of 64 years old. Participants were administered a self-report questionnaire with two items. Patients were asked to indicate their threshold for risk of amputation versus risk of death for a curative medication. Univariate statistics followed by multivariable generalized linear mixed models of risk acceptance were used to identify relationships according to age, gender, ABI, and functional claudication distance. The study results revealed older patients to be more risk tolerant with treatment. However, overall, most participants preferred conservative treatment such as endovascular revascularization which carries a lower risk rate than surgical intervention (Zafar et al., 2011).

Keeling, Naughton, O'Connell, and Lee (2008) studied quality of life in patients with PAD undergoing endovascular procedures for intermittent claudication and critical limb ischemia. Their purpose was to assess quality of life and determine if peri-

procedural medication altered quality of life. Seventy-two participants were evaluated before the endovascular procedure and one to six months following the procedure. The prospective study was conducted over a 13 month period. Angioplasty was 99% successful. Pre-procedure, patients experienced complaints of pain in the hips, thighs, or buttock during activity or at rest, arterial ulceration, or gangrene. Post procedure, patients reported improvement in pain and overall quality of life at one month followed by significant improvement at six months. Overall, patients with intermittent claudication experienced more improvement than patients with critical limb ischemia (Keeling et al., 2008).

Konstantinos et al. (2016) performed a randomized control trial to assess wound healing and quality of life with patients undergoing endovascular treatment with sirolimus-eluting stents (SES) versus balloon angioplasty for PAD. Participants receiving SES reported notable improvement in the areas of mobility and pain. Wound healing was comparable among both groups. Remes, Isoaho, Vahlberg, Viitanen, and Rautava (2010) used a cross sectional questionnaire study with a case-control methodology to compare PAD patients with controls. Patients reported a lower quality of life and higher rate of depression following treatment (Remes et al., 2010). Furthermore, patients with depressive symptoms had poorer outcomes following lower extremity revascularization than those without depressive symptoms (Cherr, Wang, Zimmerman, & Dosluoglu, 2007).

Endovascular treatment for PAD has improved over the last 10 years due to advances in technology. However, it is often difficult to conduct research on individuals with PAD due to atypical symptoms experienced. Claudication symptoms can vary

depending on age, comorbidities, and environment, making it difficult to properly diagnose. Further research in this area has the potential to have a major impact on social function, physical function, mental health, and overall quality of life for those with PAD.

Symptom Experience of Cardiovascular Disease / Endovascular Treatment

Although there is limited research on the symptom experience of endovascular treatment for lower extremity PAD, there are numerous studies surrounding experiences of patients who have undergone endovascular treatment for coronary artery disease (CAD). Throndson, Sawatzky, and Schulz (2016) conducted an interpretive descriptive study to explore perceptions of health status for patients who had undergone elective PCI for CAD. They found some participants were uncertain about future health while others felt they were cured following the procedure. Some were concerned about being asymptomatic if the blockage reoccurred. One participant was glad to have more energy following PCI. Another stated she didn't feel any different than before the procedure but was relieved that her heart would work more efficiently. Some worried other vessels were susceptible to blockages. One participant was afraid to exercise for fear of having a heart attack (Throndson et al., 2016).

Throndson et al., (2016) conducted a qualitative study to explore the symptom experience and perceptions of patients following percutaneous coronary intervention (PCI) procedures. Of the ten participants, eight were male with an average of 56 years old and two were female with an average age of 64 years old. The themes emerged from the interviews were, "what a relief, I'm better", "uncertain health", and "barriers to getting healthy" (Throndson et al., 2016, p. 27). Although a majority of participants never experienced symptoms, they felt they were better, cured, fixed, or even healthy following

the intervention. Some expressed hopes of having more energy while others said they felt no difference between pre and post-intervention. A few of the participants accepted the procedure as being part of the normal aging process but some were concerned with the fear of death or changes in lifestyle. Overall participants took an interest in pursuing a healthier lifestyle following their procedures (Throndson et al., 2016).

Kimble and King (1998) used a descriptive correlational design to study perceived benefits of percutaneous transluminal coronary angioplasty (PTCA) in patients six weeks following treatments. Findings related to participants' symptom experience included bruising and discomfort at the groin site, relief of symptoms [such as angina], fear of restenosis, and recurrent angina / perception of no benefit from PCI. Sampson, O'Cathain, and Goodacre (2008) conducted semi-structured qualitative interviews with participants undergoing primary angioplasty and found some to have feelings of denial that a cardiac event had occurred, some felt relieved at feeling "fixed" or "cured", and some felt as if nothing had happened to them following PCI. Son, Kim, and Park (2014) used a cross sectional study design and found Korean patients to have high rates of depression in the months following PCI leading to medication nonadherence. Potential reasons were hypothesized as being negative side effects from medications for greater than 6 months following their procedure such as beta-blockers, calcium channel blockers, renin-angiotensin inhibitors, aldosterone blockers, angiotensin II antagonists, vasodilators, aspirin, and statins (Son et al., 2014).

In a qualitative study, Astin, Closs, McLenachan, Hunter, and Priestley (2008) found those who had undergone PCI described their experience as going from being very ill to feeling well again. Many participants were surprised that the PCI was not more

painful than a myocardial infarction (MI). Some related the absence of their scar to being a less serious health problem. The majority of participants viewed their MI and PCI experience as a one-time event rather than a lifelong illness and believed they had been cured. The majority also voiced satisfaction at being able to perform tasks and be active following the procedure (Astin et al., 2008).

SH, Gallagher, and Elliott (2014) completed a systematic review concerning quality of life in older patients following PCI. They found the most important perceived benefits were relief of angina and improvement in quality of life. Other findings included reporting of better physical and mental function (Sh et al., 2014). Studies of symptom experiences of patients undergoing endovascular treatment for CAD are congruent with studies of PAD patients in that the studies provide evidence that patients obtain symptom relief but also may have inaccurate beliefs that their CV condition is cured.

Treatment Benefit

Patients with PAD often have a great reduction in quality of life (Fowkes et al., 2013). Even with reports of being asymptomatic, patients experience decreased mobility and decline in overall physical function (McDermott et al., 2004). However, patients respond favorably to treatment resulting in improved quality of life (Fakhry et al., 2015; Klevsgard, Froberg, Risberg, & Hallberg, 2002; Spronk, Bosch, Den Hoed, Veen, & Pattynama, 2009; Stewart, Hiatt, Regensteiner, & Hirsch, 2002). Due to the limitations of supervised exercise programs and pharmacotherapy in improving limb circulation, endovascular treatment options have been widely adopted by vascular surgeons and interventional cardiologists (Harris, Zafar, & Murphy, 2011). Endovascular treatment remains a successful treatment option for patients with intermittent claudication, critical

limb ischemia, and acute limb ischemia (Klein & Ross, 2016). This treatment option should not be utilized for prevention of amputation but reserved for symptom management and improving quality of life (Beckman, 2007). Patients also prefer minimally invasive treatment options with fewer risks of complications when available (Zafar et al., 2011). Treatment decisions by the patient and health care provider are typically based upon the severity of the disease.

A randomized control trial with a parallel design was conducted by Bo et al. (2015) to evaluate quality of life in patients with intermittent claudication following endovascular treatment for lower extremity PAD. Post-operative care was the same for both groups. The intervention group received supervised training sessions as well as home based exercise training for 12 weeks following treatment. The control group did not receive any follow up concerning exercise. Overall, the intervention group was found to have greater physical functioning (walking distance), better limb perfusion, and decreased pain as compared to the control group. Domains of social life, anxiety, and overall psychological well-being had significantly positive changes for both groups (Bo et al., 2015).

A prospective observational study was performed by Van Zitteren et al. (2015) where patients' health status was evaluated one year post treatment for PAD. All patients were offered invasive treatment, however only 39% of patients agreed to the procedure. The majority of patients' health status improved from invasive treatment but it is important to note the magnitude of benefit was lower in patients with more comorbidities and health complications (Van Zitteren et al., 2015). Typical benefits from invasive treatment for PAD includes improvement in walking ability, muscle strength and

endurance, and cardiac function (Gardner & Poehlman, 1995; Hiatt et al., 1994; Hirsch et al., 2006; Pollock et al., 2000). While these benefits are important factors for patients, goals of treatment focus on addressing the Fontaine score, alleviating symptoms and improving overall health status (Hirsch et al., 2006; Murphy et al., 2015; Norgren et al., 2007; Safley et al., 2007; White & Gray, 2007).

The CLEVER study, conducted by Murphy et al. (2015), was a randomized clinical trial that compared 6 and 18-month outcomes following stent revascularization and supervised walking versus optimal medical care for patients with moderate to severe claudication due to aortoiliac PAD. Participants in the stent revascularization group and supervised walking group had less walking impairment and less symptoms of claudication than the group with optimal medical care. However, the stent revascularization group benefitted significantly more than the supervised exercise group in the areas of symptoms, treatment satisfaction, quality of life, and overall health improvement (Murphy et al., 2015).

Gaps in Current Literature

Treatment options for PAD are becoming more readily available with the advances in percutaneous vascular interventions. Patients now have more choices to assist with symptom management strategies. The rapid evolution of treatment modalities has left a void in the literature concerning outcomes, health status, quality of life, symptom experience, and overall treatment satisfaction with the different treatment options. Previous studies have focused on hemodynamic success rates following treatment (Banerjee et al., 2012; Laird et al., 2010; Rastan et al., 2012), however there is a greater need for evaluation of meaningful individual patient outcomes (Van Zitteren et

al., 2015). Lovell, Myers, Forbes, Dresser, and Weiss (2011) emphasized the need for more evidence in the areas of patient satisfaction, behavior changes, and morbidity / mortality.

Wann-Hansson and Wennick (2016) noted few studies had been conducted about how patients communicate their experience with PAD and treatments. This affects how they adapt and adjust to their disease process because many believe they are cured after treatment. Many often lack the knowledge surrounding the disease process which puts them at risk for future cardiovascular related complications. Therefore, it is necessary to investigate how patients communicate their experience orally as well how to identify misconceptions and knowledge gaps during structured education processes (Wann-Hansson & Wennick, 2016).

Overall, there are few studies reflecting patient experiences concerning endovascular treatment for lower extremity PAD. Of the studies found, the focus appears to be on outcomes, which is more important to providers than patients, rather than on experiences of patients. Another area noted is the lack of mixed method studies as well as qualitative studies. Additionally, an overall short term and long term post-therapy quality of life evaluation has been overlooked for patients undergoing endovascular treatment for lower extremity PAD (Steunenberg, Raats, Te Siaa, De Vries, & Van der Laan, 2016). Areas of concern with quality of life would include social isolation (Aquarius et al., 2006), depression, and physical function.

Inferences for Current Study

According to Teodorescu et al., (2013), PAD is one of the most understudied and undertreated diseases globally. It affects three to ten percent of the general population

with those numbers increasing to 15% to 20% in those 70 years and older (Siracuse et al., 2016). Schorr et al., (2015) reported the most common symptom of lower extremity PAD to be claudication which includes aching, cramping, or a tired feeling in the calves or thighs as a direct result of ischemia to the muscles. Although the symptoms of PAD have been investigated, there are few studies that have documented the symptom experience and quality of life of patients undergoing endovascular procedures for lower extremity PAD and perceived benefits of treatment.

Previous research on lower extremity PAD has focused on outcomes concerning patency and limb salvage (Frans et al., 2013), however quality of life and symptom experience have not been adequately addressed. The most effective method to investigate quality of life and symptom experience is to collect subjective data concerning the patient's beliefs, expectations, and perceptions of their physical, psychological, and social status in life (Steunenberg et al., 2016). This method would allow for a deeper probing into the problem that might not be discovered with standardized questionnaires in a quantitative study. The current study investigated experiences with PAD treatment in an in-depth way. The mixed method design allowed the researcher to use standardized questionnaires to investigate common symptoms from participants and their health outcomes, but also allowed valuable qualitative data from open ended questions where they were able to identify unique experiences following endovascular treatment for PAD.

Summary

PAD is a common vascular problem often overlooked by health care providers. Patients with PAD are high risk for reduced mobility, decreased quality of life, chronic

pain, and increased mortality rate. Equally important, PAD is a significant predictor for coexisting cardiovascular events such ischemic heart disease and ischemic stroke resulting from atherosclerosis. In an effort to better understand the symptom experience of patients undergoing endovascular treatment for lower extremity PAD, SMT provided the theoretical basis for the current study. This chapter has provided a discussion of the symptom experience of patients with lower extremity PAD, current literature related to patients' experiences with treatment, and gaps in the literature which were reviewed and identified. The chapter concluded with inferences for the current study.

CHAPTER 3

METHODOLOGY

The purpose of the study was to explore the symptom experience of patients undergoing endovascular treatment for lower extremity PAD through mixed methods research. The research methods, and procedures for the current study are outlined in this chapter. The research design, setting, and sampling methods are described in detail. Instruments used to measure study variables are described along with their psychometric properties. Procedures for participant recruitment, data collection, data analysis, and protection of human subjects are also presented within this chapter.

Research Design

The research design chosen for this study was a convergent parallel mixed methods design (Creswell & Plano Clark, 2011). Mixed methods allowed the researcher to better understand the research problem by collecting complementary data in order to validate findings. Quantitative and qualitative data were collected in a web-based survey and analyzed independently, data were then compared or related, and then interpreted. During the interpretation, the researcher looked for similarity and convergence between the quantitative and qualitative results. The mixed methods approach is mainly guided from a pragmatic worldview that posits answering research questions in optimal ways is more important than a particular methodological or philosophical approach (Creswell & Plano Clark, 2011). The design was appropriate for this study because the investigator wanted to understand the symptom experience following endovascular treatment through

objectively measuring symptoms with reliable and valid tools and obtaining quantitative data regarding perceived treatment benefits and concerns.

Setting and Sample

The setting was within a web-based community as participants were recruited via social media and completed the study instruments and qualitative questions via Survey Monkey. The population studied was adults diagnosed with lower extremity PAD who had undergone endovascular treatment. Persons with lower extremity PAD was the focus of this study because PAD has a classic presentation of pain most commonly in the lower extremities while walking (Selby, 2008). Inclusion criteria for both the quantitative and qualitative strands was originally proposed as individuals who: 1) had a self-reported diagnosis of lower extremity PAD, and 2) had undergone endovascular treatment for lower limb ischemia on a non-emergent basis with no critical limb ischemia within the last five years. Exclusion criteria included persons who were: 1) experiencing critical limb ischemia and 2) had been given a treatment option of amputation for their PAD.

After launching the web-based survey, participants contacted the researcher through private messages on social media. It was determined some participants were misinterpreting language in the survey related to screening criteria for study eligibility. There was confusion concerning non-emergent versus emergent procedures and whether or not they actually were diagnosed with critical limb ischemia. The researcher clarified questions sent by participants and made changes in the survey allowing persons with lower extremity ischemia to continue with the survey regardless of their answers about the circumstances of treatment. Individuals who had undergone endovascular treatment non-emergently were included because those who underwent emergent treatment were

likely to have had a different symptom experience post-treatment than those who had non-emergent treatment. Persons who were experiencing critical limb ischemia or were presented a treatment option of amputation were likely to experience severe symptoms which might have made recalling treatment benefit from a prior procedure difficult. Consequently, they were excluded from the study.

Instrumentation

Participants completed a demographic and clinical history form and five self-report quantitative questionnaires: the Patient Health Questionnaire-9, San Diego Claudication Questionnaire (SDCQ), Walking Impairment Questionnaire (WIQ), VascuQOL questionnaire, and the Peripheral Arterial Questionnaire (PAQ). In addition, the PAD Endovascular Treatment Questionnaire, with two open-ended questions was used to collect data for the qualitative strand. Each of the instruments is described below along with its psychometric properties.

PAD Demographic and Clinical History Questionnaire

The PAD demographic and clinical history questionnaire was developed by the researcher to obtain basic demographic data from participants. This information was used to describe the sample. Data were collected concerning age, gender, race, ethnicity, marital status, medications, previous medical history, previous PCI interventions, and knowledge of blockages in the coronary arteries. Specific medical history questions were concerned with peripheral vascular disease, elevated cholesterol, history of smoking, current smoking, hypertension, diabetes, angina, and myocardial infarction. Responses

from the questionnaire provided the researcher with information that influenced symptom experiences which was not reflected in other questionnaires. A copy of the questionnaire can be found in Appendix A.

Patient Health Questionnaire-9 (PHQ-9)

The PHQ-9 was used to measure depressive symptoms and has proven to be reliable with a Cronbach's alpha of 0.96. The PHQ-9 is a self-report screening instrument with nine Likert-type items that measures the extent to which respondents have experienced symptoms of depression over a two week period. Participants rate each of the items on a scale of zero to three depending on how much the symptom has bothered them (0= not at all, 1= several days, 2=more than half the days, 3= nearly every day). Scoring is based on an algorithm based on DSM-IV criteria or a cut-off based on summed item scores. The algorithm method requires the respondent to respond to a total of five symptoms rated at least two with the exception of the suicidal ideation item. The suicidal ideation item counts as one of the five symptoms if it is rated as one or above. Another requirement is at least one of the symptoms scored at two or more is either loss of interest or pleasure or depressed mood (Manea, Gilbody, & McMillan, 2015). According to Kroenke, Spitzer, and Williams (2001) a 10th item was added to the diagnostic part of the PHQ-9 concerning work management, daily living, and relationships. The summed item score method involves obtaining the summed item score of the items to obtain a total score of 0 to 27. The cutoff score of 10 or more is recommended as a method for screening for major depressive disorder (Kroenke et al., 2001). The algorithm method might be expected to be superior to the summed item score method because it matched the DSM-IV criteria for diagnosing major depression whereas the summed item score

method does not map directly onto diagnostic criteria (Manea et al., 2015). The PHQ-9 primary care study data revealed the algorithm method had a sensitivity of 73% and a specificity of 98% (Kroenke, Spitzer, & Williams, 1999). The summed item score validation study reflecting a score of greater than or equal to 10 had a sensitivity of 88% with a sensitivity of 88% for major depressive disorder (Kroenke et al., 2001). In this study, the summed score was used to operationalize the variable of depressive symptoms. A copy of the questionnaire can be found in Appendix B.

San Diego Claudication Questionnaire (SDCQ)

The SDCQ is a seven item self-report instrument presented in a dichotomous nominal level format. This instrument is a standardized and validated revision of the WHO/Rose questionnaire (Criqui et al., 1996; Rose, 1962) in order to provide bilateral evaluation of leg-specific symptoms involving the thigh, buttock, and calf (Criqui et al., 1996). In this study, the instrument was used to assure that all participants in the study had experienced symptoms consistent with lower extremity PAD. Within the instrument, there are five possible symptom categories per leg: pain, no pain, non-calf exercise leg pain, non-Rose exercise calf pain, and Rose claudication. The SDCQ was found to be 88.1% effective in detecting intermittent claudication (Criqui et al., 1996). Interpretation of the SDCQ, according to Rose (1962), must include the following criteria to have an interpretation of intermittent claudication: 1) the site must include one or both calves, 2) onset of pain is elicited by hurrying or walking uphill, 3) pain must not begin during rest periods, 4) pain must cause the participant to stop walking or slow the pace, 5) in

majority of cases, the pain must stop within 10 minutes of stopping walking, and 6) pain must not disappear while walking. A copy of the questionnaire can be found in Appendix C.

Walking Impairment Questionnaire (WIQ)

Participants' ability to walk in terms of speed, distance and stair climbing was measured with the WIQ (Jain et al., 2012; Regensteiner, Steiner, & Hiatt, 1996). The WIQ is a 23 item instrument with three domains: walking distance, walking speed, and stair climbing. Respondents answer each item on a Likert scale from zero to four and each response is weighted based on the difficulty of the task. The walking distance score assesses walking indoors to walking 1500 feet. Zero represents inability to walk the distance while 4 represents no difficulty. The distance score is calculated by using the Likert score selected and multiplying it by the corresponding distance. The products are then totaled and a percent score is calculated. The speed score assesses walking one block at specific speeds ranging from walking slowly to jogging on a scale of zero to four. The degree of difficulty is ranked on the Likert scale and then multiplied by the weight assigned to the applicable speed question. The products are then totaled and a percentage is calculated ranging from 0-100. The stair climbing score assesses the degree of difficulty climbing a specified number of stairs ranging from one flight to three flights of stairs on a scale of zero to four. Each domain is scored on a 0-100 scale where 0 represents severe limitation and 100 indicates no impairment. The total score is multiplied by a pre-set weight for each question in the distance, speed, and number of stairs categories. The PAD Specific Questions and Differential Diagnosis sections are not included in the calculation of the total score. The products are then added and

divided by the maximum possible score. This resulting number is a percentage ranging from 0 (unable to perform any tasks) to 100 (no difficulty performing any tasks) (Jain et al., 2012; Regensteiner et al., 1996).

The WIQ was found to be a valid and reliable tool for measuring symptoms of claudication in patients with lower extremity PAD (McDermott et al., 1998; Myers et al., 2008; Regensteiner, Steiner, Panzer, & Hiatt, 1990) with a Cronbach's alpha of 0.96. Sager, Brown, Zelt, Pickett, and Tranmer (2012) found absolute claudication distance ranged from 42.3 to 1589.2 meters and peak walking time was 68-1800 seconds. Adjusted WIQ scores were positively and moderately associated with the log transformed absolute walking distance and peak walking time ($r > .53$, $p < .001$). An overall WIQ score of 42.5 or less correlated with lower performers (sensitivity 0.90, specificity 0.73) while the subscale score of distance and stairs of 75.5 or greater correlated with higher performers (sensitivity 0.41, specificity 0.90) (Sager et al., 2012). A copy of the questionnaire can be found in Appendix D.

VascuQol-25

The VascuQol-25 is a twenty-five item, self- report questionnaire developed in 2001 to measure quality of life and treatment options in patients with lower limb ischemia as the result of PAD. It has shown to be a reliable and valid tool to measure outcomes in these patients (Morgan, Crayford, Murrin, & Fraser, 2001; Nordanstig, Karlsson, Pettersson, & Wann-Hansson, 2012). According to Morgan et al. (2001) quality of life measurements were consistent concerning disease severity and age, regardless of gender, making the VascuQol-25 appropriate for all patients with lower limb ischemia. Reliability was greater than 0.90 in stable patients' test-retest scores.

All items showed internal consistency with a Cronbach's alpha of 0.98. The questionnaire was also shown to be responsive to change ($p < .001$) (Morgan et al., 2001).

Within the 25 items, there are five subscales, or domains, consisting of pain (four items), symptoms (four items), activities (eight items), social (two items), and emotional (seven items). Each question is presented in a Likert format ranging from one (all of the time) to seven (none of the time). The responses are averaged to obtain an overall score as well as an individual domain score ranging from one (worst health related quality of life) to seven (best health related quality of life. A strength of the instrument is the lack of documented gender bias (Nordanstig et al., 2012). The VascuQOL-25 was found to be reliable and showed face and construct validity in assessing quality of life for those experiencing PAD (Morgan, et al., 2001). Although this instrument has been deemed a quality of life instrument, it provided a strong measure of symptoms along with emotional response to symptoms and consequently, selected subscales were used to operationalize symptoms in this study. A copy of the questionnaire can be found in Appendix E.

Peripheral Artery Questionnaire (PAQ)

The PAQ was developed by Dr. John Spertus (Spertus, Jones, Poler, & Rocha-Singh, 2004) to assess symptoms, quality of life, treatment outcomes, and overall disease management (Hoeks et al., 2009) for patients with PAD undergoing percutaneous peripheral revascularization. This instrument has been used to measure symptomatic PAD before, during, and after revascularizations (Je et al., 2015) and has been found to be valid and reliable (Hoeks et al., 2009; Lee, Cho, Spertus, & Kim, 2012; Spertus et al.,

2004). The seven domains of the PAQ were internally reliable with a Cronbach's alpha of 0.80-0.94. Test-retest reliability had non-statistically significant mean changes of 0.6-2.3 points. The PAQ was highly sensitive to clinical improvement after revascularization with scores changes ranging from 13.7 to 41.9 points ($p < \text{or} = .001$ for all) (Spertus et al., 2004).

The PAQ is a 21 item self-report questionnaire presented in Likert scale format. The first question involves location and severity of symptoms (right leg, left leg, both are same, or neither). Questions 2a-2f (six items) address physical functioning and assesses the limitation of routine daily activities due to PAD. The activities chosen were sex-neutral and widely applicable. The third question addresses symptom stability and is used to describe symptom improvement or deterioration. Questions four, five, and six are used to describe how frequently the patient is affected by symptoms of PAD. Questions seven, eight, and nine assess the treatment satisfaction score and measure how satisfied participants are with their current treatment plan. Questions 10, 11, and 12 address quality of life and measure life satisfaction as a result of the limitations of PAD. Question 12 is a mental health question and has been found to be a powerful predictor of depression which can greatly affect psychological well-being and prognosis in PAD. Questions 13a-13c refer to the social limitation score and measures quality of life (Spertus et al., 2004).

The PAQ is used to assess symptoms of PAD over the previous four weeks (Spertus et al., 2004). The six domains include: symptoms, symptom stability (change in symptoms), physical limitation, treatment satisfaction, social functioning, and quality of life. Subscales for each of the domains are calculated and the scoring involves summing

the individual items within a domain and completing calculations such that the possible range of scores for each subscale is 0 to 100 with higher scores indicating better quality of life. A total score can also be calculated from the subscale scores. Symptom stability scores greater than 50 or less than 50 indicate recent improvement or worsening of symptoms whereas a score of 50 represents no change over the past four weeks. In addition to basic symptom assessment, the PAQ can be utilized to identify, monitor, and track symptoms and quality of life for patients who are being considered candidates for revascularization (Safley et al., 2011). A copy of the questionnaire can be found in Appendix F.

PAD Endovascular Treatment Questionnaire

The PAD Endovascular Treatment Questionnaire was developed by the researcher to elicit data about participants' perceptions of benefits from endovascular treatment for PAD, along with their concerns. The first item asks, “Tell us about the benefits you have received from having your PAD treated with an endovascular procedure. What benefits of treatment were most important to you and why were these benefits important to you? Provide as much detail as possible." The second question item states, “Along with the benefits of treatment, patients with peripheral arterial disease sometimes report they have had concerns when undergoing treatment. What concerns did you experience while undergoing your endovascular procedure(s)? How did you deal with these concerns? Provide as much detail as possible.” A copy of the questionnaire can be found in Appendix G. Appendix H contains all the instruments integrated into one document including the study screening questions. This closely approximates what the participant viewed within the web-based survey.

Procedures

Institutional review board (IRB) approval (Appendix I) was obtained from Mercer University prior to implementing the study. Participants were recruited via the social media site Facebook. Facebook has 1.44 billion monthly users globally and 161 million active daily users in North America (Facebook Q1 205 Results, 2015), which can offer an opportunity to advertise the study to many unique and hard to reach individuals. Referrals occurred through sharing a Facebook page, known as online snowballing (King, O'Rourke, & DeLongis, 2014), where the researcher described a need for recruiting participants who had undergone endovascular treatment for PAD. Utilizing social media for research allowed participants to respond during down time when they were more likely to take part in a survey. Altruism research indicates the willingness to help others is heightened when it is presented at opportune times (Hui et al., 2009). Paulhus (1998) also found the data to be less biased by impression management when completed in the privacy of one's home. A link to the Survey Monkey survey with study instruments was included within the Facebook page. According to King et al. (2014), this particular recruitment approach allowed the participants to complete the study survey at their leisure as well as eliminate data transfer time, thus reducing data entry cost and chance for error.

Following IRB approval, the researcher created a Facebook page where a detailed explanation about the study was displayed. The Facebook page link was posted on the researcher's home page with a comment concerning the nature of the research. Snowball sampling was used by asking users to share the page with their personal Facebook friends (Boyce, Schanding, Backscheider Burridge, & Keller-Magulis, 2013; Mannix, Wilkes, &

Daly, 2014). The Facebook page for the research, known as the splashpage, provided detailed information concerning the study (King et al., 2014). In this study, a link to the web-based consent and survey including the open-ended questions was embedded in the Facebook post. After clicking on the link, respondents were presented with a set of screening questions to ensure they met inclusion / exclusion criteria. If their answers to these questions revealed they were not eligible for participation, they were thanked for their interest and requested to close their browser. Those who were eligible to participate proceeded to a web-based informed consent and following consent were presented with the study questionnaires that were generated in the web-based survey.

Overview of Data Analysis

Data analysis occurred by evaluating data graphically and identifying trends as well as applying statistical models to the data (Field, 2013). Quantitative data collected within the web-based survey were exported into Microsoft Excel. Text data in response to open-ended questions from the PAD Endovascular Treatment Questionnaire were copied and pasted into a Microsoft Word document for qualitative analysis. The Excel file with quantitative data were imported into IBM Statistical Program for the Social Sciences (SPSS) for data cleaning and analysis. Descriptive statistics were used to examine frequency distributions and percentages for nominal and ordinal level data and measures of central tendency for interval / ratio level data. All interval / ratio level data were examined for normality to assure they met assumptions of parametric statistics. The Microsoft Word document with text data were optimized for qualitative coding including the creation of larger margins and the numbering of lines within the text.

Data Analysis Plan per Research Question

In this section, the data analysis specific for each research question is discussed. The independent and dependent variables for the research questions were operationalized with multiple instruments, subscales within instruments, and individual items. Tables one and two summarize what items in the questionnaires were used to measure study variables.

Research question 1: *What is the symptom experience (leg pain / discomfort, other symptoms, emotional response to symptoms) of patients following endovascular treatment for lower extremity PAD?* Research question 1 was addressed by using descriptive statistics. The symptom experience of patients was characterized with specific emphasis on leg, thigh, buttock, and calf pain and discomfort such as weakness, tingling sensations along with emotional response to symptoms. Additional symptoms, such as shortness of breath, were also examined. Table 1 summarizes the operationalization of variables in research question 1.

Table 1. *Operationalization of Variables for Research Question 1*

Variable	Instrument	Subscale and instrument item number	Possible range of scores	Level of Measurement
Leg pain / discomfort	VascuQOL	Pain domain subscale 1 pain/walk, 7 pain/night 13pain/rest, 20 pain/ distress	1-7 (average of items)	I/R
	SDCQ	1 pain walk 2 pain still / sitting 3a pain calves 3b pain thighs 3c pain buttocks 4 pain walk uphill/hurry 5 pain walk ordinary pace 6 pain disappear while walk	0-1 (present vs. absent)	Nominal
Other symptoms	WIQ	1- joint pain, 2 leg weakness 3 chest pain 4 SOB 5 heart palp.	0-4 (scored per item)	Ordinal
	VascuQOL	Symptoms domain subscale 3 cold feet 5 legs tired 8 numbness 17 ulcer	1-7 (average of items)	I/R
Emotional response to symptoms	VascuQOL	Emotional domain subscale 2 worry/injury 11 concern/ housebound 12 concern/ poor circulation 19 poor circulation frustration 21 guilty about relying 23 worry about losing foot 25 depression about poor circ.	1-7 (average of items)	I/R

Note. WIQ=Walking Impairment Questionnaire; SDCQ=San Diego Claudication Questionnaire; I/R= interval / ratio

Research question 2: *Are person factors (age, gender), health and illness factors (diabetes, depression), and symptom experience (leg pain, discomfort, other symptoms, emotional response to symptoms) correlates of quality of life following endovascular treatment?* Research question 2 was addressed using Pearson product moment correlations.

Table 2 summarizes how each of the variables in research question 2 were operationalized. Correlations were evaluated for statistical significance along with their direction and magnitude.

Table 2. *Operationalization of Variables for Research Question 2*

Variable	Instrument	Instrument item # or subscale	Possible range of scores	Level
Age, gender, diabetes	Demographic & Clinical History Form	1, 2, 3	Continuous	Age-I/R Gender-Nom. Diabetes-Nom.
Depression	Patient Health Questionnaire-9	1-9	0-27	I/R
Leg pain / discomfort	VascuQOL	Pain domain subscale		I/R
Other symptoms	WIQ	1- joint pain, 2 leg weakness 3 chest pain 4 SOB 5 heart palpitations	0-4	ordinal
	VascuQOL	Symptom domain subscale	1-7 (average of items)	I/R
Emotional response to symptoms (focused on post-treatment)?	VascuQOL	Emotional domain subscale	1-7/ (average of terms)	I/R
Symptoms	PAQ	4, 5, 6	0-100	I/R
Stability	PAQ	3	0-100	I/R
Physical Function	PAQ	2a-f	0-100	I/R
Social Function	PAQ	13a-c	0-100	I/R
Treatment satisfaction	PAQ	7, 8, 9	0-100	I/R
Quality of life	PAQ	10, 11, 12	0-100	I/R
PAQ Summary Score	PAQ	Mean of physical function, symptoms, quality of life, and social limitation subscales	0-100	I/R
Walking	WIQ	Speed, distance, stairs domain subscales	0-100	I/R

Note. WIQ=Walking Impairment Questionnaire; PAQ= Peripheral Arterial Questionnaire; I/R= interval / ratio

Research questions 3 and 4 (qualitative questions): *What are patients' perceptions of benefits of endovascular treatment for lower extremity PAD?* and *What are patients' concerns following endovascular treatment for lower extremity PAD?* were assessed using qualitative data obtained from open-ended items on the PAD Endovascular Treatment Questionnaire. Qualitative data were analyzed using the procedural steps outlined by Creswell and Plano Clark (2011) which involved: 1) preparing the data for analysis, 2) exploring the data, 3) analyzing the data, 4) representing the data analysis, and 4) interpreting the results. The data were coded using coding methods described by Saldaña (2009) and analyzed using procedural steps recommended by Creswell and Plano Clark (2011).

Research question 5: *Do the quantitative data and qualitative data converge around the symptom experience of patients with PAD?* To address this research questions, themes and subthemes identified in the qualitative data were compared with the quantitative findings for congruence and incongruence. Direct quotes of participants were used to help explain and clarify the quantitative findings.

Justification for Sample Size

The power analysis for the study was based on research question 2 that involved parametric statistics using Pearson Product Moment correlation. According to Cohen (1988), an *r* of .30 is considered a medium effect. With a two-tailed alpha of .05, a sample size of 84 participants provides a power of .80 to detect a statistically significant correlation of .30. Consequently, a sample size of 84 participants was proposed.

Protection of Human Subjects

Prior to conducting research, the protocol was approved by Mercer University Institutional Review Board (IRB). Self-report questionnaires were used to collect data using a web-based survey. Participants were provided with a web-based consent which assured them that participation in the study was voluntary and the option to withdraw from the study at any time was available simply by closing the web browser. All web-based data were collected such that participants provided no identifying data.

The information from the questionnaires was entered into a secure database with a secure login / password and a corporate level firewall. Consistent with Mercer IRB protocol, all study related materials were secured and kept confidential for protection of human subjects. Paper copies of all research data were locked in a filing cabinet in the researcher's office behind a locked door. Electronic copies of data and other study related documents were secured in a corporate level firewall protected computer.

Summary

The purpose of the study was to explore the symptom experience of patients undergoing endovascular treatment for lower extremity PAD using a cross-sectional approach. The research methodology for this study has been outlined in this chapter. Research design, setting, and sampling methods were described in detail. Instruments used to measure study variables were described as they applied to each research question, along with their psychometric properties. Procedures for participant recruitment, data collection, and data analysis were also discussed. The chapter concluded with justification for the study sample size and description of measures used for the protection of human subjects.

CHAPTER 4

RESULTS

This chapter provides the results of this mixed methods research study. The sections of this chapter will include a description of the sample and the data analysis used to address each of the five research questions. Approaches to data analysis of both the quantitative and qualitative strands and each strand's associated findings are discussed.

Management and Preparation of Data for Analysis

Quantitative data analysis was conducted using SPSS 22.0. Raw data from the web-based survey were imported into an Excel file and cleaned using established protocols (Pallant, 2016). Normality assessments were conducted for interval / ratio level data. All data were normally distributed with the exception of scores from the Walking Impairment Questionnaire (WIQ) instrument. Assumptions for statistical tests were assessed prior to running parametric analyses. Frequencies were calculated for all study variables and missing data were assessed. The approach to missing data was as follows. Instrument developer guidelines were used to handle missing data for the PAQ. Data missing at the item level were labeled as missing data, no imputations were performed, and they were excluded from the analysis. Pearson's product moment correlations were used to examine relationships among normally distributed variables, while Spearman's rho was used to assess the relationships among non-normally distributed data.

Description of Sample

Originally, the intent of the researcher was to only recruit participants from the United States. However, once the Facebook page was promoted and shared, it became clear that those diagnosed with PAD from other countries were eager to participate. While country of residence was not a variable collected on the survey, anecdotal data in Facebook conversations included interactions with individuals from England, Australia, and Canada. Several participants indicated a desire to participate in the study in an effort to help others diagnosed with the disease, even if they themselves did not benefit from the research.

A total of 456 people accessed the Facebook page created by the researcher. Of those 456 people, 276 people "liked" the page and began following it. A total of 119 participants accessed the survey after providing the web-based informed consent. Of the 119 participants, two provided informed consent but did not begin to complete the survey. Fifteen participants partially completed the screening questions and did not continue with the survey. Eleven participants completed the screening questions but did not move forward with the survey. Ninety-one participants completed demographic information, however, 26 did not have complete survey information. Those with incomplete data were excluded from the final analysis yielding 65 participants with complete data. Figure 2 depicts the flow diagram for how the final analytic sample was identified.

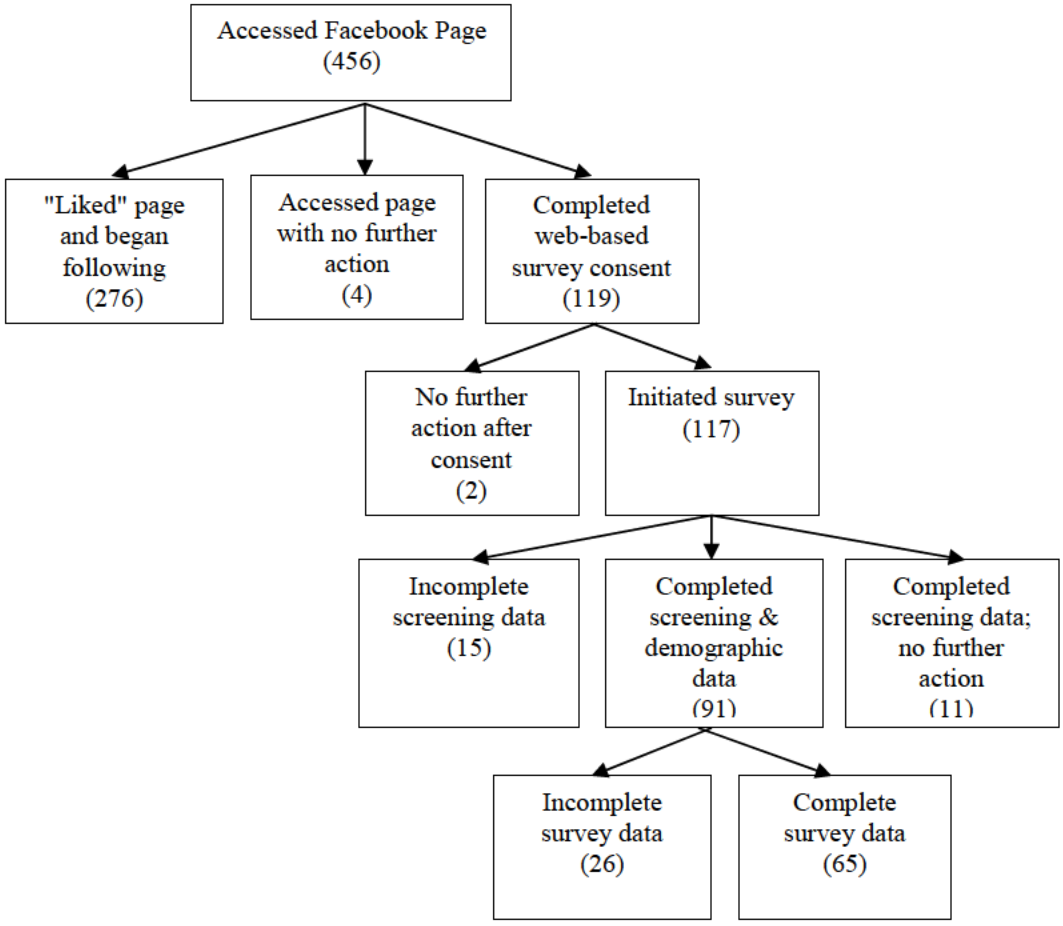

Figure 2. Generation of Analytic Data Set

Note. Number in parentheses indicates number of individuals in each category.

Table 3 summarizes the demographic characteristics of the sample. The age of participants ranged from 36 to 73 years with a mean of 57 years. The majority were white, non-Hispanic, married females. A majority reported the following risk factors / comorbidities: a history of smoking (81.5%) and hypertension (61.5%). Over a quarter of the sample had diabetes (26.2%). Common medications among participants included antiplatelets (89.2%), antihyperlipidemics (75.4%), antihypertensives (70.8). Eighty-

seven percent of reported having previous endovascular procedures other than in the heart. In addition, 76.9% reported non-emergent balloon or stent procedures.

Table 3. *Demographic Characteristics of Sample (N=65)*

	N	Percent	Mean (SD)
Age in years			56.9(8.15)
Gender			
Male	17	26.2	
Female	48	73.8	
Race			
Black / African American	2	3.1	
White	62	95.4	
American Indian or Alaska Native	1	0.01	
Ethnicity			
Hispanic / Latino	3	4.6	
Non-Hispanic / Latino	62	90.8	
Marital Status			
Single	7	10.8	
Married	34	52.3	
Divorced	14	21.5	
Widowed	5	7.7	
Long-term Relationship	5	7.7	
Comorbidities			
Hyperlipidemia	39	60	
History of smoking	53	81.5	
Current Smoker	21	32.3	
Hypertension	40	61.5	
Diabetes	17	26.2	
Angina	8	12.3	
Myocardial infarction	10	15.4	
CVA	4	6.2	
Medications			
Antihyperlipidemic	49	75.4	
Antihypertensive	46	70.8	
Diuretics	14	21.5	
Antiplatelets	58	89.2	
Antidiabetics	14	21.5	
Antidepressants	24	36.9	
Symptom relief	13	20	
	57	87.7	
Previous Endovascular Procedures (other than cardiac)			
Blockages in heart	17	26.2	

Note. SD = standard deviation

The data from the San Diego Claudication Questionnaire (SDCQ) and the first nine items of the Walking Impairment Questionnaire (WIQ) were used to describe the sample. The data from WIQ "other symptoms" item were used to address research question one. Psychometric properties for study instruments and their individual subscales / domains are presented in Table 4. According to Pallant (2016), Cronbach's alpha values of 0.70 or greater are considered acceptable, however values above 0.80 are preferred. Cronbach's alpha for the WIQ, PHQ-9, VascuQOL-25, and PAQ instruments ranged from 0.93-0.98 indicating very good internal consistency reliability.

Table 4. *Measures of Central Tendency and Psychometric Properties of Study Instruments*

Instrument	# of Items	*n**	Cronbach's α	Possible range of sum score	Observed range of sum score in sample (median)	M(SD)
Walking Impairment Questionnaire (WIQ)	14	60	0.96	0-100	0-96.5 (11.6)	24.6(27.4)
Distance	7	61	0.96	0-100	0-100(4.2)	19.4(28.5)
Speed	4	65	0.92	0-100	0-100(10.9)	27.2(30.2)
Stair Climbing	3	64	0.95	0-100	0-100(16.7)	26.6(30.2)
Patient Health Questionnaire-9 (PHQ-9)	9	61	0.94	0-27	0-27(9.00)	11.0(8.5)
Vascu-QOL-25	25	56	0.98	1-7	1.12-6.96 (3.3)	3.7(1.7)
Pain	4	63	0.88	1-7	1-7(3.3)	3.5(1.7)
Symptoms	4	62	0.82	1-7	1-7(4.9)	4.6(1.6)
Activities	8	64	0.94	1-7	1-6.88(3.2)	3.5(1.7)
Social	2	62	0.92	1-7	1-7(3.5)	3.8(2.04)
Emotional	7	61	0.95	1-7	1-7(3.3)	3.7(2.0)
Peripheral Arterial Questionnaire (PAQ)						
Symptoms	3	64	0.88	0-100	0-100(30.6)	37.1(31.1)
Stability	1	65	N/A	0-100	0-100(50.0)	47.3(27.6)
Physical Function	6	47	0.93	0-100	0-100(25.0)	31.7(28.4)
Treatment Satisfaction	3	62	0.97	0-100	0-100(54.2)	51.1(35.2)
Social Limitation	3	65	0.90	0-100	0-100(41.7)	41.8(32.7)
Quality of Life	3	65	0.92	0-100	0-100(25.0)	33.0(30.1)
Summary Score	4	65	0.93	0-100	0-100(33.3)	36.2(28.4)

Note. * Number of participants who answered all items, this *n* is used for the Cronbach's α and the range of the sum score in the sample; M = mean; SD = standard deviation

Data Analysis by Research Question

Prior to main analyses to address research questions, data were evaluated to determine if they met statistical assumptions for parametric analyses. Frequency distributions were generated for nominal and ordinal data. Bivariate correlations were used to examine relationships among variables.

Research question 1- *What is the symptom experience (leg pain / discomfort, other symptoms, emotional response to symptoms) of patients following endovascular treatment for lower extremity PAD?*

The San Diego Claudication Questionnaire (SDCQ) results are reported by frequency and percent in Table 5. Initially the SDCQ was included in the study for screening purposes, however, the researcher made the decision to analyze the data and include the information about leg pain to help characterize the sample. Slightly over one-third of the sample were experiencing pain in both calves when walking and experiencing pain in both legs when walking uphill or hurrying. Forty percent were experiencing bilateral leg pain when walking at an ordinary pace. The majority of participants reported stopping walking when pain occurred.

Table 5. *San Diego Claudication Questionnaire Frequency / Percent (N=65)*

Item	Frequency	Percent
Pain / discomfort / numbness when walking		
Right leg	13	14.9
Left leg	6	6.9
Both legs	36	41.4
Pain in left calf	13	14.9
Pain in right calf	21	24.1
Pain in both calves	28	32.2
Pain in left thigh	9	10.3
Pain in right thigh	16	18.4
Pain in both thighs	19	21.8
Pain in left buttock	12	13.8
Pain in right buttock	12	13.8
Pain in both buttocks	16	18.4
Pain walking uphill or hurrying		
Right leg	16	18.4
Left leg	2	2.3
Both legs	29	33.3
Pain walking at an ordinary pace		
Right leg	13	14.9
Left leg	3	3.4
Both legs	36	41.4
Pain disappears while still walking		
Right leg	5	5.7
Left leg	0	0
Both legs	3	3.4
Action if pain occurs while walking		
Stop	50	57.5
Slow down	13	14.9
Keep moving at the same pace	0	0

Table 6 reflects data from the WIQ where participants were asked to rate different symptoms while walking ranging from none to very symptomatic. The majority of participants (92.3%) had pain. Approximately 88% of participants reported weakness. Less than half of participants (46.1%) reported chest pain. Fifty-two percent of participants reported shortness of breath. The majority of the sample did not experience heart palpitations or chest discomfort.

Table 6. *Walking Impairment Questionnaire (Other Symptoms) Frequency / Percent (N=65)*

	Frequency	Percent
Degree of Pain		
Very	14	21.5
Much	15	23.1
Some	20	30.8
Slight	11	16.9
None	5	7.7
Degree of Weakness		
Very	16	24.6
Much	20	30.8
Some	15	23.1
Slight	6	9.2
None	7	10.8
Degree of Chest Discomfort		
Very	1	1.5
Much	2	3.1
Some	16	24.6
Slight	11	16.9
None	34	52.3
Degree of Shortness of Breath		
Very	3	4.6
Much	5	7.7
Some	15	23.1
Slight	11	16.9
None	31	47.7
Degree of Heart Palpitations		
Very	1	1.5
Much	2	3.1
Some	16	24.6
Slight	10	15.4
None	34	52.3

Note. Some percentages do not add up to 100% due to missing data

Using data from the WIQ and SDCQ, the researcher was able to identify the symptoms experienced by participants following endovascular treatment. Despite having received treatment, the majority of participants continued to have pain and weakness in the legs, calves, and thighs when walking. Pain occurred when walking at an ordinary pace and while walking uphill or in a hurry. Of those who experienced pain while

walking, the majority reported stopping to rest until the pain subsided before resuming walking. The majority of the sample did not experience chest pain or palpitations, however, many did experience shortness of breath.

Research question 2 - *Are person factors (age, gender), health and illness factors (diabetes, depression), and symptom experience (leg pain, discomfort, other symptoms, emotional response to symptoms) correlates of quality of life following endovascular treatment?*

This study involved multiple instruments. In some instances, single instruments operationalized different constructs within Symptom Management Theory (SMT). To increase conceptual clarity and to assure more robust statistical analysis by planning what variables would be correlated with each other a priori, instrument total scores and subscales were categorized according to the SMT theoretical components. Table 7 summarizes which study variables were used to operationalize person, health, and illness factors, the symptom experience, and outcomes. The Symptom Management Model concepts of person, health, and illness factors were represented using the study variables of age, gender, diabetes, and depression. Symptom experience was represented with the study variables of the VascuQOL pain and symptoms domain as well as the PAQ symptoms and stability domains. These domains accurately represented what the participant experienced in terms of symptoms following their treatment. The outcomes component was measured using the VascuQOL activities, emotional, and social domains, WIQ total score, and PAQ physical function, social function, treatment satisfaction, and quality of life domains. These domains represented the participants' physical, emotional, social, and mental state following treatment as well as overall quality of life. Using a

systematic approach, the following correlational analyses were conducted: person, health, and illness (PHI) variables were correlated with symptom experience variables, PHI variables were correlated with outcome variables, and symptom experience variables were correlated with outcome variables. Each of these correlational analyses will be discussed separately.

Table 7. *Theoretical Components and Study Variables*

SMM Theoretical Components	Study Variables
Person / Health / Illness Factors	Age Gender Diabetes Depression
Symptom Experience	VascuQOL Pain Domain VascuQOL Symptoms Domain PAQ Symptoms Domain PAQ Stability Domain
Outcomes	VascuQOL Activities Domain VascuQOL Emotional Domain VascuQOL Social Domain WIQ Total Score PAQ Physical Function Domain PAQ Social Function Domain PAQ Treatment Satisfaction Domain PAQ Quality of Life Domain

Note. SMM=Symptom Management Model; PAQ=Peripheral Arterial Questionnaire; WIQ=Walking Impairment Questionnaire

Relationships Between Person, Health and Illness Component and Symptom Experience Component of Symptom Management Theory

Table 8 summarizes the correlations between the PHI variables and symptom experience variables.

Table 8. *Pearson Product Moment Correlations Between Person, Health, and Illness Variables and Symptom Experience Variables*

	Age	Gender	Diabetes	Depression
VascuQOL Pain	.37**	-.22	-.01	-.71**
VascuQOL Symptoms	.46**	-.18	-.02	-.71**
PAQ Symptoms	.27*	-.23	-.11	-.61**
PAQ Stability	.14	-.06	.28	-.35**

Note. PAQ=Peripheral Arterial Questionnaire, * $p < .05$, ** $p < .01$

Correlational analysis was performed to examine relationships among person, health, and illness variables and symptom experience variables. Significant correlations were noted with age and VascuQOL pain domain ($r=.37$, $p<0.01$), age and VascuQOL symptoms domain ($r=.46$, $p<0.01$), and age and PAQ symptom domain ($r=.27$, $p<0.05$). Greater age was associated with lesser pain, symptoms, and difficulty with symptoms reported following endovascular treatment. When depression was correlated with the VascuQOL symptoms domain ($r= -.71$, $p<0.01$) and PAQ symptoms domain ($r= -60$, $p<0.01$), results suggested lower depression was associated with lower overall symptoms following endovascular treatment. Similarly, depression and VascuQOL pain domain ($r= -.71$, $p<0.01$) had a significant negative correlation suggesting lower depressive symptoms was associated with lower pain symptoms. Depression and stability domain were also negatively correlated ($r= -.35$, $p<0.01$) suggesting greater depressive symptoms was associated with more difficulty controlling symptoms following endovascular treatment. Gender and diabetes were found to have no significant correlations with symptom experience variables.

Relationships Between Person, Health, and Illness Variables and Outcomes Components of Symptom Management Theory

Table 9 summarizes the correlations between the PHI variables and the outcomes variables.

Table 9. *Pearson Product Moment Correlations Between Person, Health, and Illness Variables and Outcomes Variables*

	Age	Gender	Diabetes	Depression
VascuQOL Activities	.33**	-.21	.08	-.72**
VascuQOL Emotional	.38**	-.23	.05	-.79**
VascuQOL Social	.33**	-.23	.05	-.67**
WIQ Total Score	.49**	-.34**	.11	-.58**
PAQ Physical Function	.39**	-.30*	.02	-.65**
PAQ Social Function	.27*	-.16	.01	-.74**
PAQ Treatment Satisfaction	-.04	-.06	.07	-.48**
PAQ Quality of Life	.23	-.27*	.03	-.77**

Note. PAQ = Peripheral Arterial Questionnaire, WIQ = Walking Impairment Questionnaire, * $p < .05$, ** $p < .01$

There were significant correlations between age and all of the outcomes variables except the PAQ treatment satisfaction and PAQ quality of life domains. Older age was associated with being more active, having less walking impairment, having better physical function, having less emotional symptoms, and participating in more social activities following endovascular treatment. Analysis revealed significant negative

correlations between gender and physical function domain ($r= -.30$, $p<0.05$) and gender and WIQ total score ($r= -.34$, $p<0.01$) suggesting men had better physical functioning and walking ability than women following endovascular treatment. The variables of gender and PAQ quality of life had a highly significant negative correlation indicating men have a better overall quality of life than women. The variable of depression was significantly correlated with all of the outcomes variables. Participants who reported less depression were more social, more physically active, had better walking ability, experienced less emotional symptoms, had greater treatment satisfaction, and reported an overall better quality of life following endovascular treatment.

Relationships Between Symptom Experience and Outcomes Components of Symptom Management Theory

Table 10 summarizes the relationships between the symptom experience variables and the outcomes variables, however, correlations within instrument subscales were not reported.

Table 10. *Pearson Product Moment Correlations Between Symptom Experience Variables and Outcomes Variables*

	VascuQOL Pain	VascuQOL Symptoms	PAQ Symptoms	PAQ Stability Domain
VascuQOL Activities	-	-	.76**	.43**
VascuQOL Emotional	-	-	.71**	.39**
VascuQOL Social	-	-	.74**	.33**
WIQ Total Score	.73**	.70**	.63**	.27*
PAQ Physical Function	.84**	.79**	-	-
PAQ Social Function	.76**	.76**	-	-
PAQ Treatment Satisfaction	.45**	.32*	-	-
PAQ Quality of Life	.80**	.79**	-	-

Note. PAQ = Peripheral Arterial Questionnaire, WIQ = Walking Impairment Questionnaire. *p < .05, **p<.01

Each of the symptom experience variables were significantly correlated with all of the outcomes variables. When comparing VascuQOL pain and symptoms domains with the outcomes variables, participants who reported less pain and less symptoms reported significantly better walking ability, better physical functioning, greater participation in social activities, greater treatment satisfaction, and greater overall quality of life than participants who reported more pain.

When comparing the PAQ symptoms variable with the outcomes variables, participants who reported less problems with symptoms after treatment were significantly more active, reported less emotional symptoms, reported better social functioning, and

better walking ability than those who reported more problems with symptoms after treatment. Similarly, when comparing the PAQ stability variable with the outcomes variables, participants who indicated less problems controlling symptoms after treatment were also significantly more active, reported less emotional symptoms, reported better social functioning, and better walking ability than those who reported more problems with symptoms after treatment.

Research Questions 3 and 4

Research question 3, *What are patients' perceptions of benefits of endovascular treatment for lower extremity PAD?* was associated with the qualitative portion of the study. Study participants were asked, "Describe the benefits you have received from having your PAD treated with an endovascular procedure. What benefits of treatment were most important to you and why were these benefits important to you? Provide as much detail as possible". Research question 4, "*What are patients' concerns following endovascular treatment for lower extremity PAD?"* was addressed by having study participants answer the following, "Along with the benefits of treatment, patients with peripheral arterial disease sometimes report they have had concerns when undergoing treatment. What concerns did you experience while undergoing your endovascular procedure(s)? How did you deal with these concerns? Provide as much detail as possible". Qualitative data were obtained through the use of two open-ended questions in the web-based survey. Participants were instructed to type their responses into the provided text box and asked to provide as much detail as possible.

Creswell and Plano Clark (2011) identified the first step in data analysis as preparation of data. Open ended qualitative question responses were copied verbatim

from the web-based survey, pasted into a Word document, and prepared for printing. Responses were matched to participant numbers and lines were numbered on the Word document for ease of reference and coding purposes. Qualitative data were then transferred into a code book where margins were widened and appropriate spacing was added to provide adequate coding space for documentation and organization. Raw qualitative data were only accessible to the researcher, dissertation chair, and internal committee chair member. There were 65 responses to the open-ended questions used to address research question three and 71 responses to the open-ended questions used to address research question four in the web-based survey. To assure an adequate corpus of data, respondents who provided qualitative data but were not included in the quantitative sample because of missing questionnaire data were retained in the qualitative data for analysis.

Confidentiality was continuously maintained by keeping the hard copy of the qualitative data and codebook in a locked cabinet in the researcher's office behind a locked door. Electronic copies were stored in a password protected computer with a corporate level firewall. The coding process was initiated using descriptive and in vivo methods outlined by Saldaña (2013). Descriptive coding was used to illustrate dense descriptions in the data by using short phrases. In vivo coding was employed by extracting verbatim responses to capture specific experiences of participants. Once first cycle coding was completed, the researcher met with the committee chair and internal committee member. The committee chair and internal committee member both completed first cycle coding as part of the peer review process. Peer review was used during the analytic phase. During the peer review process, first cycle coding was found

to be sufficient due to the fact that all three coders identified similar themes and subthemes. Three themes and two subthemes emerged during the coding process of data used to address research question three. One theme and four subthemes emerged during the coding process of data used to address research question four. Each of the themes and subthemes will be discussed using verbatim quotes and short phrases. A thorough description of the themes and subthemes identified through the coding process of the qualitative data is provided below.

Trustworthiness and rigor was ensured using Guba's (1981) model, which has been used by regularly by nurses and educators. This model has identified four aspects of trustworthiness that were relevant to this study: (a) truth value, (b) applicability, (c) consistency, and (d) neutrality. These aspects are important in that they guide the researcher to increase rigor and assess the value of the research.

Truth value was interpreted as whether the researcher was confident in the truth of the findings in the data and established credibility. Truth value was determined by the discovery of the human experience participants perceived following endovascular treatment for PAD. Recurrent themes and patterns were evaluated from the responses. This process of data collection ensured strong credibility (Lincoln & Guba, 1985).

Applicability referred to the ability to apply the findings of the data to other groups or settings. Sufficient descriptive data were presented from participants to allow for comparison, thus addressing applicability. Applicability also referred to transferability which occurred through comparison of the sample to the demographic data in this study and consideration of the data separately than the subjects.

Consistency was based on the fact that there was something out there to be discovered and could potentially be used as a benchmark. Consistency of the findings also relates to dependability. Dependability was ensured through peer examination of data in order to enhance credibility.

Finally, neutrality is the absence of bias in the research procedures and results (Sandelowski, 1986). Lincoln and Guba (1985) suggested confirmability be the basis of neutrality which occurs when truth value and applicability are established. Neutrality was established and maintained throughout the data collection process, ensuring truth value and applicability. Prolonged engagement was not present between the researcher and participants, however, reflexivity was utilized to self-assess in order to avoid influence from the researcher's background and perceptions by using a field journal.

Theme and Subthemes

Research question 3 - *What are patients' perceptions of benefits of endovascular treatment for lower extremity PAD?* The theme and four subthemes that emerged from the qualitative data concerning treatment of benefit were:

1. Continuum of Benefit
    a. Clear benefit
    b. In between
    c. Revolving door
    d. No benefit

Continuum of Benefit

Responses to the survey questions about benefit varied in length from a brief phrase to several sentences in length. The theme of *continuum of benefit* emerged as

participants described the benefits that were most important to them following treatment for their endovascular procedure. Under this theme, it became clear that some participants had obvious benefits with no complications. Others had no benefit from the procedure. Some participants had short-term benefits with a cyclical pattern requiring further procedures. Subthemes identified within the *continuum of benefit* were *clear benefit, in-between benefit, revolving door,* and *no benefit.*

The subtheme of *clear benefit* emerged when participants described the positive outcomes of their endovascular procedure. Participants reported clear benefits concerning avoiding amputation due to lack of blood flow to the extremities. One participant stated,

> Balloon angioplasty in groin allowed blood flow to return to normal. I had like 20% blood flow before procedure and in danger of losing my leg. Benefit was it allowed me to keep my leg and return to somewhat normal functioning, walking.

Another participant identified her benefit as, "I am no longer in danger of amputation and the grafts are open. I am mobile and out of the majority of pain. The benefits are pretty self-explanatory." An additional participant stated, "My leg and foot were saved! My foot was turning purple due to no blood flow." Based on the responses, avoidance of amputation was a highly salient benefit. The participants noted improvement in color of the limb which could clearly be monitored and could serve as a gauge for disease improvement.

Other clear benefits identified were increased physical functioning / walking ability and decreased pain. Immobility due to pain emerged as a common concern of participants. One participant stated,

> The pain has gone and I am able to walk further, and stand longer. I stop having cramps when I am sleeping. Being able to walk further and longer was very

> important to me helping me maintain more independence, in doing my housekeeping and shopping.

Another participant identified similar results and stated, "The treatments received relieved the pain so that I could continue being active and walking to ensure better cardiovascular and overall health." Additionally, one participant noted she had total pain relief and stated, "I was immediately out of pain. The pain of my iliac artery being 100% blocked was excruciating pain, not just when walking, but at rest, just sitting or when trying to sleep." A different participant also had total relief stating, "Following my procedures, the pain in both of my legs disappeared. I was able to resume normal activity." One of the participants had a major change in physical functioning stating, "I had a stent put in my iliac artery which was 99% clogged. I can now walk without pain, I could barely walk five feet before." Responses reflected an overall decrease in pain and increase in physical functioning / walking ability, which were positive outcomes from the endovascular procedures they received.

A few participants made more generalized comments regarding benefits from their endovascular procedures. One participant stated, "I had iliac artery stents put in I feel great no issues at all." Another stated, "Following my procedures, I was able to resume normal activity." In addition, one said they were, "able to perform daily activities and my quality of life returned to normal." Although these data were non-specific concerning direct physical benefits, it is clear participants believed they benefitted from their procedures.

The subtheme of *in-between benefit* reflected the experience of participants who described some positive outcomes of their endovascular procedure, but the benefit was not as complete as they hoped or anticipated. Typically, the procedure yielded pain relief

but did not lead to the increased activity they desired. Fifteen participants reported having in-between benefit from their procedure, which left them with some symptoms and limitations with physical activities. One participant stated he could "walk more without pain. Having less pain was important." Another stated, "Since [the procedure], I still deal with some pain especially when walking or climbing stairs and or hills." Additionally, a participant revealed, "angioplasty in my right leg did improve the aching and pain, but I still couldn't walk further." Only one participant commented on temperature of the extremity stating, "My feet are warmer but I still have numbness and pain in the calves, thighs, [and] buttocks."

The subtheme of *revolving door* emerged when participants described having access to the healthcare system repeatedly for the same endovascular problems. The participants required multiple procedures related to the chronic and unrelenting nature of PAD and felt as if they were constantly having to have another procedure, sometimes with little to no benefit. One participant stated, "When the stents were put in (the third time) I could walk much better than prior to the surgery. However, I've never been able to walk as far as I could before coming down with P.A.D." Another participant stated,

> I have had stents placed twice within 3 months. First time it only lasted about a month to six weeks. Second time it didn't last a month. I was 100% blocked with only a trickle of blood flow. I was told that the only other option was a bypass.

After multiple procedures, one participant who ultimately had arterial bypass stated, "My very first procedure in 2010 did the best. The other six, (balloons, angiogram stent placement etc) did not do very well for improvement. I kept having reoccurring issues until having a bypass April 2017." Another participant stated he had, "only temporary

relief. The first procedures in 2014 lasted three years most recent still have muscle pain legs. Three procedures just in last three months with little relief." The cause for re-occlusion was unclear in these participants, but results reflected little to no benefit despite multiple endovascular procedures. Although PAD is not curable, as the disease progresses, procedures hold symptoms at bay for a limited time but eventually symptoms reappear as the disease continues to progress.

The subtheme of *no benefit* emerged when participants described their negative experiences concerning outcomes of their endovascular procedures. Of the 71 participants who provided qualitative data for this question, nine (12%) reported no benefit. One participant's language reflected frustration stating, “I had no benefits. I have no insurance so I'm fighting a losing battle with this disease.” Another reported, “No benefits in pain management still can't walk or stand for a while.” In addition, another participant stated, “Did not work. Blockage is too long.” One other claimed she had no relief stating, “I have never had relief from stents [or] balloons. They fail pretty quickly for me. I have had stents fail in 24 hours.”

Research question 4 - *What are patients' concerns following endovascular treatment for lower extremity PAD?* The three themes and two subthemes that emerged the qualitative data concerning patients' concerns were:

1. Outcome
2. Process
3. Coping
    a. Trust
    b. Communication

Outcome

The theme of *outcome* materialized as participants described their physical and emotional experiences while undergoing endovascular procedures. There were many concerns expressed within the data. One participant stated she was worried about, "dying on the table or having a stroke or heart attack during the procedure." Four participants were concerned with the risk of amputation during the procedure. Nine participants were worried about having an unsuccessful procedure or need for future procedures with one stating,

> You worry about the risks and then worry about whether the procedure will be successful and if it is, how long the graft/stent will remain open & functioning. Always in the back of your mind is the strong possibility of amputation.

Four participants verbalized fears of pain during the procedure and four participants stated they had no concerns at all regarding the procedure.

Process

The theme of *process* reflected participants' thoughts, fears, and concerns while undergoing the endovascular procedure. One participant recalled they were concerned about "being placed on Plavix for only six weeks after the procedure. I really think that if I had been left on it longer or permanently, my first stents would have lasted. Maybe not, but that was my thinking." Another participant recalled a negative experience stating,

> The procedure with the stents was a nightmare, I ended up being totally awake and in the worse pain of my life, screaming and crying they finally knocked me out and I woke in ICU. Honestly, it was like torture and I'm terrified of anymore [procedures].

Four participants were concerned about the lack of pre-procedural information given. Two participants verbalized a fear arterial bleeding or accidental puncture of a vessel

during the procedure. Other individual concerns regarding the theme of *process* included nerve damage, surgical repair due to a hematoma, blood clots, infection, and plaque breaking loose.

Coping

The theme of *coping* unfolded as participants expressed different ways they dealt with some of the circumstances surrounding their endovascular procedure(s). Each individual coped with situations differently based on surroundings, information provided, and support systems and some participants were coping better than others. Two participants had multiple procedures and felt that, experiencing those procedures, "has been helpful in putting most concerns to rest." One participant commented it was, "hard for my family to understand the pain and difficulty. I look good so people don't understand that I'm not good. It is really scary, every pain and ache worries me." Another appeared frustrated saying,

> I think that I'm running out of options. I have to go three hours from home to get to vascular doctor, so long time to worry about it [and] almost have a panic attack. I have lost so much to this, I can't go where I want. Can't walk in grass, sand, uneven ground. Sometimes can't hardly make it through the grocery store.

Two participants felt medication was necessary to help alleviate anxiety. One participant commented they "took one xanax the night before and the morning of the surgery and don't even remember going to hospital." Another participant found a unique approach to help with his questions and concerns stating,

> I just accepted it and wanted to be a good example for others. Plus, [I] created the PAD support group on Facebook. It's a big help for me, and everyone seems to have a thousand questions that no one doctor can address.

Spirituality also played a role in responses. Some dealt with concerns through prayer. A participant stated,

> I dealt with this by praying that all would go well and placing my trust in God's hands. I also was concerned that I would have a stroke or heart attack during the procedure. Again, I dealt with that through prayer.

These comments indicated there were social, psychological, and physical limitations due to the PAD disease process, thus making it difficult to manage day-to-day life.

Two subthemes of *trust* and *communication* began to appear under the theme of *coping* during analysis of the qualitative data as participants described how they managed their concerns. It appeared to be crucial for patients to trust their healthcare providers to avoid misunderstandings and disappointments. One participant expressed her persistence by "relying on my health care providers to answer, explain, draw pictures, and teach me about each and every step of any procedure, treatment or surgery. I ask, ask and ask some more about everything." It appeared that the subtheme of *trust* was equally as important between the healthcare provider and God. One participant stated, "I just trusted in the surgeon and left it in God's hands, truly." A different participant stated, "Since it all happened fast, there was no option for dealing with it." Through prayer, trust in God, and trust in the healthcare provider, participants were able to effectively manage their fear and anxiety related to the procedure.

Communication was also an important subtheme related to coping. Effective communication allowed participants to discuss concerns, ask questions, and receive feedback from their healthcare providers. This interaction appeared to alleviate anxiety and reduce misunderstandings between the patient and healthcare provider. Some participants had positive experiences. One participant stated, "I had concerns only because the procedures were new to me but my doctor answered my questions pretty well." Another participant had a long-term relationship with their provider and stated the

"vascular consultant has been treating me for over nine years [and] explains everything well." One participant offered advice to others stating, "Keeping an open and honest communication with your medical provider and team should alleviate most [concerns]." Similarly, another participant said she communicated with her healthcare provider by writing down, "all my questions/concerns and went over them with the staff and doctors." Another participant stated, "Laying still for so long is painful. I have talked to my doctor and had him promise he wouldn't let me be in pain." Along with the positive responses, there were also negative responses concerning communication. Some felt as if they did not receive adequate information from their healthcare provider. One participant said, "doctors don't explain things good enough or give you options." Another stated they were not "given enough information. Plain and simple. Not being given the risks and benefits. Not being completely evaluated in other areas for the disease. Having to constantly push for good care and worry something is being missed." One participant felt the provider misrepresented information when she stated,

> I didn't expect anyone but the cardiologist doing the procedure but he didn't do it at all and it wasn't explained to me that he wouldn't be doing it but would be there. I believe I should have been asked or at least told that it wouldn't be him doing the angioplasty.

Communication emerged as a key factor in participants' ability to deal with treatment both in the short and long term.

Research question 5 - *Do the quantitative data and qualitative data converge around the symptom experience of patients with PAD?*

Following analysis of both qualitative and quantitative data, results were merged and examined for convergence (Creswell & Plano Clark, 2011). Qualitative data related to benefits and concerns following endovascular treatment supported the quantitative data

related to symptom experience (leg pain / discomfort, other symptoms, emotional response to symptoms). In the quantitative strand, those with less pain were more physically active, more social, and had greater treatment satisfaction than those with greater pain after treatment. Those who reported less symptom problems and better controlled symptoms were more active, more social, experienced less emotional symptoms, and better walking ability. The majority of participants' responses to qualitative research question 3 suggested they received some benefit and treatment satisfaction from their procedure, which were grouped under qualitative themes of *clear benefit* and *in-between* benefit. Responses included pain relief, greater walking ability and mobility, decreased edema, and avoiding amputation. This was demonstrated in the qualitative data in the themes of *clear benefit* and *in-between benefit* where participants verbalized they had less pain and less difficulty with mobility / walking. The subthemes of *trust* and *communication* under the theme of *coping* were supportive of treatment satisfaction as well in that participants verbalized trusting in their healthcare providers and discussing concerns with them, which likely led to a better overall experience with their procedure. Participants also expressed concerns of fear of the procedure not working, nervousness, pain management, and establishing trust with their healthcare provider which all can be placed on the continuum of benefit theme as well as associated with outcomes, process, and coping themes.

Quantitative data related to person factors, (age, gender) and health and illness factors (diabetes, depression) were examined in relation to qualitative data regarding participants' concerns following endovascular treatment for PAD. Quantitative data results showed older participants reported better outcomes, better quality of life, less

depression, and greater mobility than younger participants. However, qualitative data did diverge from the quantitative data and showed younger participants identified as having *clear benefit* from the procedure. The mean age of the 47 participants who provided qualitative data was 56.94 (SD 7.31). Of the 24 participants who experienced *clear* benefit, the mean age was 56.5 (SD 7.22) years. Of the 9 participants who experienced *no benefit*, the mean age was 58.8 (SD 5.95) years. However, the mean age of the 6 participants who were part of the *revolving door*, was the lowest at 55.3 (SD 10.71) years. Overall, qualitative and quantitative data did not converge around age.

Gender was correlated with quality of life in the quantitative strand as well as in the qualitative strand. Quantitative data suggested women had less physical function and less walking ability compared to men thus contributing to poorer quality of life. This finding was congruent with the qualitative data. The sample from the qualitative data was predominantly female with 38 females and 10 males. Seventy percent (n = 7) of males and 44.7% (n = 17) of females reported *clear benefit*. All participants (n=9) who reported the *in-between* benefit were female. Twenty percent (n=2) of males and 10.5% (n=4) of females reported those experiencing the *revolving door effect*. Ten percent (n=1) of males and 21.1% (n=8) of females who reported *no benefit* from their procedure. Overall, a greater percentage of males reported clear benefit compared to females demonstrating convergence of the quantitative and qualitative findings around gender and quality of life.

Diabetes was not found to be correlated with outcomes in the quantitative strand, which diverged from the data in the qualitative strand. Of the 48 participants in the qualitative strand 10 had diabetes and 38 did not have diabetes. Thirty percent (n = 3) of

participants with diabetes were in the *clear benefit* group compared to 55% (n = 21) of participants without diabetes. While 23.6% (n= 9) of participants without diabetes reported *in-between benefit*, none of the participants with diabetes reported *in-between* benefit. Additionally, the remaining 70% (n = 7) of participants with diabetes experienced the *revolving door effect* or *no benefit*, compared to 21% (n = 8) of the participants without diabetes. Overall, the qualitative data suggest participants without diabetes experienced greater treatment benefit than those with diabetes.

In the quantitative strand, participants with higher PHQ-9 scores also had a poorer quality of life, were less active, less social, and had worse symptoms than those with lower PHQ-9 scores. Quantitative data were congruent with qualitative data. Using a PHQ-9 cutoff score of 10 (Kroenke et al, 2001), 19 of the 39 participants who provided qualitative data had scores indicative of major depression. Of the 39 participants, the mean depression score was 11.56 (8.91). Of the 18 participants who reported *clear benefit* from their procedure, the mean PHQ-9 score was 10 (SD 10.02). Thirty-nine percent (n=7) of those participants reported scores indicating depression. Eight participants reported *in-between* benefit with a mean PHQ-9 score of 10.13 (SD 6.31), with 37.5% (n=3) reporting scores indicating depression. Six participants reported *revolving door effect* with a mean PHQ-9 score of 11 (SD 8.94). Fifty percent (n=3) of those participants reported scores indicating depression. Seven participants reported *no benefit* from the endovascular procedure with a mean PHQ-9 score of 17.71 (SD 7.13). Eighty-six percent (n=6) of those participants reported scores indicating depression. Overall participants in the *no benefit* group indicated higher levels of depression

compared to those in the other *continuum of benefit* groups indicating convergence between the quantitative and qualitative data.

Summary

This chapter presented a description of the study sample and strategies for management and preparation of data for analysis. Descriptive statistics and psychometric properties on all data collection instruments used in this research study were also reported. In addition, quantitative and qualitative findings were reported for each research question. A description of the strategies used to ensure trustworthiness and rigor was also presented. The chapter concluded with a discussion about how the quantitative and qualitative data converged to answer the mixed methods research question.

CHAPTER FIVE

DISCUSSIONS AND RECOMMENDATIONS

This chapter includes a discussion of the results of study findings. Strengths and limitations of the study are outlined and explained. In addition, recommendations for nursing practice and future nursing research are proposed. The purpose of this study was to explore the symptom experience of patients undergoing endovascular treatment for lower extremity PAD using a convergent parallel mixed methods design. The mixed methods approach allowed the researcher to obtain a more thorough understanding of participants' experiences following endovascular treatment.

Discussion of the Findings

The conceptual basis of this study was the Symptom Management Model. The model was used to frame the discussion of the study findings. The sample for this study was predominantly middle-aged white women who were experiencing high symptom burden. High symptom burden has been found to be associated with greater psychological distress, greater functional impairment, and lesser utilization of healthcare (Creed & Barsky, 2004). While the majority of individuals reported clear treatment benefit, there were individuals who continued to be symptomatic despite multiple procedures.

Person, Health, and Illness Findings

Person (age and gender), health, and illness factors have been associated with health outcomes. In the current study, younger age was associated with worse symptoms and outcomes. However, research surrounding age and PAD symptoms and outcomes has resulted in mixed findings. Some studies found older individuals with PAD to be at higher risk for adverse events and to have a significantly worse quality of life than younger individuals (Hooi, Stoffers, Knottnerus, & Van Ree, 1999; Shan, Saxena, McMahon, & Newcomb, 2013). Huang et al. (2016) reported no differences in outcomes of older and younger individuals with PAD following endovascular treatment and Lee, Beasley, and Adams (2015) reported similar outcomes among younger and older individuals following endovascular procedures despite older individuals having more advanced disease. A study by Lepantalo, Houbballah, Raux, and LaMuraglia (2012) supported Lee et al.'s findings purporting that younger individuals (less than 65 years of age) with PAD were of great concern and likely had worse symptoms due to their aggressive disease process and poor outcomes following intervention.

When comparing individuals with PAD to those with coronary artery disease (CAD), older individuals with CAD were reported to more often present with atypical pain when compared to younger individuals (Ahmed et al., 2013). Older individuals were also more likely to have worse clinical outcomes due to misdiagnosis or inappropriate interventional therapies. In addition, older individuals were at a higher risk for re-occlusion, complications, and death than younger individuals (Ahmed et al., 2013). Poor prognosis in this population may be due to factors associated with advanced age (Alexander, Newby, & Cannon, 2007; Rosengren, Wallentin, & Simoons, 2006), more

co-morbidities (Chang et al., 2017), advanced cardiovascular disease and / or left ventricular dysfunction (Jaber et al., 1999), and / or misuse of recommended treatment therapies (Alexander et al, 2007; Alexander, Roe, & Chen, 2005; Rosengren et al., 2006). Findings for the current study were inconsistent with literature concerning CAD. In this study, younger individuals had worse outcomes, more difficulty controlling symptoms, and a higher incidence of depression than older individuals. Although individuals with PAD often present with atypical symptoms (Ahmed et al., 2013), younger individuals were found to have less mobility and worse outcomes. This may be due to the debilitating nature of the disease and the fact that younger individuals do not typically experience as much physical limitation as older individuals as a result of the natural aging process, consequently physical limitations are more salient for them.

Women with PAD reported worse outcomes in the current study following endovascular treatment than men. Reasons for this included greater depression, less physical functioning, more physical impairment, and overall worse quality of life. Prior to 2003, little data existed on women with PAD due to the fact that most research and clinical trials focused on whole populations or populations consisting of men (Vavra & Kibbe, (2009). According to Teodorescu et al., (2013), Caucasian men were historically the most prominent gender and race to develop PAD. Doshi, Shah, and Meraj (2017) reported that although women present later in the disease process typically, they have better outcomes than men. Men were also found to have higher complication rates following endovascular intervention than women (Doshi et al., 2017).

Other studies suggested women may have a greater risk for developing PAD than men (Breveti et al., 2008; Sigvant et al., 2007). The physiological differences between

men and women and the time necessary to properly diagnose PAD may contribute to the worse outcomes in women with PAD (Diehm et al., 2004; He et al., 2006; Moussa et al., 2009; Sigvant et al., 2007). Women have been found to present with unusual signs of PAD and other coexisting comorbidities, which makes a definitive diagnosis difficult. Teodorescu et al. (2013) suggested women may experience more from impairment from their disease, keeping them home and causing them to be less likely to seek treatment from a healthcare provider. This can lead to delays in diagnosis and treatment in this population. Teodorescu et al. (2013) suggested women more often present with advanced disease, have a poorer quality of life, and impaired lower extremity function. Women also describe more physical dysfunction, pain, and mood disturbances than men, thus resulting in decreased quality of life related to depression (Oka, Szuba, Giacomini, & Cooke, 2003). Smolderen and Pelle (2003) reported women who were newly diagnosed with PAD had a four times greater chance of developing depression than men. While PAD risk factors appear to be similar among men and women, men were also two times more likely to have better risk factor control than women (Cacoub et al., 2009). Additionally, Kunadian et al. (2017) found women with CAD had a higher complication rate and overall mortality rate than men following endovascular treatment as well as a greater risk for future revascularization. These findings may be the result of women having more co-morbidities such as diabetes, PAD, renal disease, and cardiovascular disease than men (Alfredsson, Stenestrand, Wallentin, & Swahn, 2007; Scirica et al., 1999).

Depression and depressive symptoms were highly salient in the current study and were associated with multiple symptoms and outcomes such as pain, decreased mobility,

and decreased social interaction leading to isolation. The literature supports that poor outcomes after treatment of lower extremity PAD has been associated with depression (Cherr et al., 2007). There is limited data linking psychological variables and atypical symptom reporting in PAD compared to CAD. However, patients with atypical symptoms of CAD have been found to suffer from depression (Sheps, Creed, & Clouse, 2004). Likewise, Smolderen et al. (2008) found individuals with PAD suffered from depression, anxiety, and anhedonia. The loss of physical function in individuals has also been found to greatly impact their mental health (Wann-Hansson, Hallberg, Klevsgard, & Anderson, 2005). Those who reported pain at rest and atypical symptoms were found to have a higher incidence of depression and the highest symptom burden. Potential reasons for depression in this population are heightened awareness, uncontrolled pain, persistent symptoms, and disability (Smolderen et al., 2008).

Healthcare providers managing patients clinically with PAD should be aware of the correlations between gender, symptoms, atypical symptoms, and psychological factors in order to manage patients more effectively. Chronic illness in individuals with cardiovascular disease is linked to depression as a result of individuals' inability to cope with their physical and psychological state (Di Benedetto et al., 2014). This can be related to the absence of meaningful activities in their lives, socialization, and overall attitude (Arseven, Guralnik, O'Brien, Liu, & McDermott, 2001; Mays et al., 2011; Pratt, Norris, & Kaufmann, 2005; Treat-Jacobson et al., 2002). These negative emotions have a direct effect on physical function, symptom experience, perception of individual health, and quality of life (Liles, Kallen, Petersen, & Bush, 2006). The ability and willingness to incorporate coping resources into daily life can determine how individuals manage their

stressful events (Herbert, 1997). Inability to cope accompanied by depression can have a significant impact on individuals' future physical and mental health status (Di Benedetto et al., 2014).

Risk factors for PAD include smoking, age, diabetes mellitus, hypertension, and dyslipidemia with diabetes and smoking being among the highest risk factors (Lloyd-Jones et al., 2009). According to Zulfiqar (2017), 77% of those diagnosed with diabetes develop some type of cardiovascular disease. This is due to the presence of obesity, hypertension, dyslipidemia, and / or insulin resistance (Zulfiqar, 2017). Therefore, it is not surprising in the current study that individuals with PAD without diabetes reported greater treatment benefit than those with diabetes. Duration of illness has also been found to be a significant risk factor for developing PAD. Korhonen et al. (2009) reported that those with diabetes for 10 years or longer were at a much higher risk for developing PAD than those with a diagnosis of pre-diabetes or newly diagnosed diabetes. The current study did not identify the length of time participants had been diagnosed with diabetes. This may have been a key factor in the reason more symptoms were not reported depending on the length of time individuals have been diagnosed with diabetes or pre-diabetes within this cohort.

Individuals with coexisting diabetes and PAD have a greater risk of poor outcomes (including amputation) and decreased quality of life than those only diagnosed with PAD. Although individuals with PAD have a substantial risk for mortality, those with diabetes have a significantly greater mortality 10 years post-intervention than those without diabetes (Mueller, Hinterreiter, Poelz, Haltmayer, & Dieplinger, 2016). These results are supported by the current study. Individuals with diabetes have calcification in

the vascular system, which may contribute to pain in the feet and legs. This may affect differentiating diabetic pain from PAD pain. (Klonizakis, Manning, Lingham, Donnelly, and Yeung (2015) found those with diabetes had a more rapid PAD disease progression than those without diabetes based on microcirculatory findings in their population. These findings could result in skin ulcerations and further deterioration of the extremity, potentially resulting in amputation (Klonizakis et al., 2015). Data from studies with individuals having coexisting CAD and diabetes were similar. Hee et al. (2012) reported poorer outcomes and higher complication rates in those with CAD and diabetes than non-diabetic patients with CAD following endovascular intervention.

Symptom Experience

The symptom experience expressed by the individuals in this study following endovascular treatment was consistent with the literature. The goal of endovascular treatment is to relieve the debilitating pain from claudication and restore or improve physical function in patients. The majority of individuals in this study reported pain relief and increased physical function following treatment. Symptoms from claudication in PAD are most commonly reported as exertional leg, calf, thigh, or buttock pain due to arterial obstruction that subsides with rest (Klein & Ross, 2016). This is very different from other cardiovascular diseases in that individuals commonly present with chest pain, palpitations, and / or shortness of breath. Symptoms associated with PAD are unique, making it difficult to compare with the presentation of other cardiovascular disease processes. However, the symptom experience is more comparable with PAD and CAD. With both disease processes, symptoms are typically relieved with rest prior to treatment. Once treated, individuals are generally able to increase physical activity and have

decreased or no pain. According to Wann-Hansson and Wennick (2016), individuals with PAD reported a sense of relief that the treatment was successful. Others felt uncertain that the procedure was successful (Wann-Hansson & Wennick, 2016). These findings were confirmed in the current study through qualitative data. Some participants were relieved that the procedure was successful and happy to have decreased pain and increased mobility. Others reported wondering if the procedure would be successful and fearing possible amputation.

Symptom clusters are often used to describe particular symptoms associated with disease processes. For example, most cardiovascular disorders, such as acute coronary syndrome, myocardial infarction, and heart failure, are associated with one or more symptoms such as chest, pain, palpitations, shortness of breath, decreased activity, and / or diaphoresis, which is very different from the symptom experience of PAD. According to Schorr et al., (2015), the most common symptom reported with PAD is claudication. Seven percent to 33% of patients reported claudication as part of their symptom experience, while the remainder of individuals reported atypical symptoms such as burning in the quadriceps (Schorr et al., 2015). Diagnosing PAD has been particularly challenging to healthcare providers because the majority of individuals have an unusual presentation of symptoms. As a result, identification of symptom clusters associated with PAD have not been established which may be a reason it has not been clearly documented in the literature.

While the current study did not examine symptom management strategies, it may have proven beneficial to explore that aspect of PAD. The goals in symptom management for PAD are pain control, restoring perfusion, preventing or healing

ulcerations, and avoiding amputation (Ali & Carman, 2012). In addition to endovascular intervention to restore perfusion, individuals may have benefitted from other symptom management strategies. Individuals with better symptom control may have participated in supervised walking programs, which has been identified as a foundation for decreasing symptomatic PAD (Hirsch et al., 2006). Pharmaco-therapy was briefly examined in the current study and the majority of individuals were taking antiplatelets, cholesterol lowering medications, and antidepressants. These medications are prescribed improve symptom management by decreasing the chances of a thrombotic event, increasing circulation, and improving mental health. Once a diagnosis of PAD has been made, smoking cessation is strongly recommended. The majority of individuals in the current study had a history of smoking (81.5%, n=53). Other than the strategies mentioned above, exploring symptom management strategies used by individuals to improve their quality of life may have helped to better understand the symptom experience. These strategies may have resulted in less symptoms and better management of pain.

Outcomes

Endovascular treatment for PAD has the potential to significantly improve quality of life in individuals by decreasing pain and increasing mobility. Individuals undergoing endovascular treatment have been found to require less assistance in daily activities, greater ability to shop and participate in physical activities (Egberg, Mattiasson, Ljungstrom, & Styrud, 2010). In the current study, individuals' outcome following endovascular treatment ranged from being asymptomatic to having worse symptoms than prior to treatment. However, the majority of individuals reported improvement in quality of life following treatment. Some individuals expressed gratitude that they did not

require leg amputation. Others discussed the ability to walk further without pain and participate in activities such as shopping, housework, and social functions. Some of the individuals identified initial relief from the procedure, but eventually benefits disappeared and impaired mobility and pain resumed. There were some individuals who received no benefit or worsening symptoms following the procedure. According to Tepe et al. (2015), patients with restenosis or no benefit from stent therapy often require revascularization. The variation in outcomes in these individuals may be related to advanced disease, comorbidities, advanced age, and compliance with treatment regimens. Poor outcomes from endovascular treatment can greatly impact patients' quality of life (Remes et al., 2010) and has the potential to contribute to isolation, decreased socialization, and depression.

Recommendations for Nursing Practice

A vital component of nursing practice is effective communication with patients, families, and providers. Nurses educate patients about their illness, the disease process, and symptom management strategies and encourage patients to ask questions and request clarification when they need more information. However, patients often experience uncertainty prior to having invasive procedures even though it can improve quality of life and may not retain information provided or feel uncomfortable asking additional questions (Wann-Hansson & Wennick, 2016). With this awareness, nurses must provide education to patients prior to, during, and following endovascular procedures for PAD and ensure patients are aware of common symptoms such as pain and depression, which should be reported to their healthcare provider. Patients may have unrealistic expectations of procedures, such as the impression that the endovascular procedure will

provide a cure (Wann-Hansson & Wennick, 2016). Therefore, patients require education regarding lifelong care associated with PAD. While there is no cure for PAD, there are effective ways to manage symptoms. Nurses play a vital role in communicating with patients concerning illness management, which may lead to an improvement in quality of life.

Early screening and detection is a key factor in diagnosing PAD (Conte & Vale, 2017). Nurses are at the forefront of patient care. It is essential for nurses to be aware of potential symptoms and screening procedures associated with PAD in order to report findings to the healthcare provider to facilitate early diagnosis. Patients with PAD have been found to be at high risk for alterations in mood. While screening for PAD is important, the process should also include screening for mood disorders, such as depression, due to the impact the disease has on quality of life (Smolderen et al., 2008).

Recommendations for Future Nursing Research

PAD has been difficult to diagnose in the past due to vague or non-traditional symptoms in some individuals (Federman & Kravetz, 2007). PAD is emerging as a troublesome yet manageable disease when diagnosed properly. This researcher believes PAD will be even more aggressively diagnosed in the next decade thus leading to larger numbers of patients managing a diagnosis of PAD. Healthcare providers must be diligent in screening and investigating vague symptoms. Women with PAD are of particular concern due to their underrepresentation because they often delay seeking treatment or are misdiagnosed due to vague or atypical symptoms associated with the disease (Barochiner et al., 2014). It would be beneficial to study co-morbid issues of women

such as depression, older age, and targeted interventions to address their complicated situations.

Healthcare providers would benefit from more qualitative research, especially semi-structured interviews with individuals diagnosed with PAD using their own words to describe specific concerns in greater detail. This data could provide insight about events leading to diagnosis of PAD, specific symptoms associated with PAD, availability and adequacy of education provided after diagnosis, and level of understanding of the recommended treatment plan. Prompting from the interviewer would allow individuals to elaborate on ideas and provide rich data. This method could provide more insight into the impact of the symptom experience of individuals with PAD undergoing endovascular treatment as well as the influence of age, gender, and race on those with the disease. This method could also provide information concerning the impact of genetics, noncompliance, lack of access to medical treatment or counseling, and / or lack of healthcare provider experience with procedures.

An additional area warranting research is the study of individuals with PAD and associated renal disease. According to Selby (2008), individuals who are most likely to develop PAD are those with known atherosclerosis, chronic renal disease and diabetes. This study included questions about hyperlipidemia and diabetes, but did not include questions about renal disease. There may also be benefit in exploring the role of diabetic neuropathy and arthritis in patients with PAD. Symptoms of stiffness and immobility and / or bone, joint, and nerve pain may be due to other disease processes rather than from PAD alone. Another factor associated with diabetes and PAD is the length of time individuals have been diagnosed with diabetes. Individuals with advanced diabetes may

have worse outcomes than those who are newly diagnosed. Therefore, it would be pertinent to know the length of time individuals have been diagnosed with diabetes as it is associated with symptoms of PAD.

While diabetes and smoking are the largest risk factors for PAD, other studies have shown no change in PAD prevalence with a decline in smoking and more aggressive risk factor management (Cassar, Coull, Bachoo, Macaulay, & Brittenden, 2003; Willingendael et al., 2004). This information may suggest a possible genetic link with this disease rather than an associated risk factor. Further research is warranted to investigate a correlation between PAD and genetic predisposition of individuals.

Strengths of the Study

One strength of this study was using a mixed method approach. This allowed the researcher to obtain rich data from the qualitative questions while quantitative data provided statistical data, thus strengthening and validating the research. Another strength was the more global response received when the Facebook page was shared. Individuals from multiple countries sent private messages asking for permission to participate in the study. The ability to access individuals from other countries would not have been possible without access to the World Wide Web.

According to Criqui et al. (1996), individuals 60 years of age and older are at risk for developing PAD. The mean age for the current study was 56 years. Due to the debilitating nature of PAD, individuals have the potential to have physical limitations. Utilizing Facebook to reach out to this population allowed the researcher to access individuals who may not have been available to be interviewed in a traditional manner. According to the Pew Research Center (2014), six out of 10 senior citizens regularly

access the internet as of 2012. Of those accessing the internet, "81% use social networking sites such as Facebook to socialize with others on a daily or near daily basis" (Pew Research Center, 2014, p. 5). This method of accessing individuals allowed the researcher to obtain information that otherwise may not have been accessible.

Limitations of the Study

One of the limitations of the study was many participants did not complete the survey questionnaire. Potential reasons may include the length of the survey, disinterest, lost internet connection, or they may have felt as if the questions did not apply to them. Another limitation was the accidental elimination of a question from the San Diego Claudication Questionnaire (SDCQ). This occurred during the creation of the web-based survey and was unintentionally overlooked. However, this question was not likely to have had a meaningful impact on the outcomes of the study due to the fact that the SDCQ was only used to describe the sample.

Another limitation was identified as participants accessed the survey in the first week of the study. Many participants posted comments on the Facebook page or sent a private message to the researcher upon completion of the survey. Some comments included, "shortest survey ever taken" and "it cut me off after a few questions". Upon further investigation, a problem was discovered in that the participants were likely misinterpreting some of the questions. Some participants interpreted their procedures as being surgery when, in fact, they had undergone an invasive procedure. Others considered their procedure to be life threatening or emergent when it was not. In response to this issue, the researcher altered the web-based survey to allow participants to

continue the survey regardless of their answers to the screening questions. This change caused an influx of participants being able to complete the survey with quality data.

The findings of this study should be generalized with caution, as it is likely the data are not representative of the patient population. An additional limitation of the study was the inability to reach the proposed sample size. Had the targeted sample size been obtained it is possible that different relationships may have been identified. Due to the fact that a limited number of participants were obtained using Facebook, a different sampling plan may have yielded greater participation. A larger variety of geographical backgrounds with a more diverse population could have possibly strengthened the study as well. However, access to these individuals could be limited due to rules and regulations enforced by the Health Insurance Portability and Accountability Act of 1996 (HIPAA). While the researcher's intent was to access individuals through local medical facilities, that was not a viable option. The medical facilities selected did not return calls or refused to participate in the study. Those who refused stated legal concerns regarding patient privacy. Alternative options may have included contacting individuals through senior centers, churches, and / or pharmacies.

The final limitation noted in the current study was the majority of the sample consisted of white females. While research is lacking in females with PAD, this disease has been found to occur across all races and genders and findings should be generalized to males and racial / ethnic minorities with caution. As mentioned previously, the majority of research concerning PAD has occurred with white males, therefore it is important to examine other populations to better understand the impact of this particular disease.

Summary

This chapter discussed the major findings of the research study as well as recommendations for nursing practice, and future nursing research. Strengths and limitations were also discussed. The findings of this study have the potential to improve the symptom experience as well as overall care for individuals who have undergone endovascular treatment for PAD.

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APPENDICES

APPENDIX A

PAD DEMOGRAPHIC AND CLINICAL HISTORY QUESTIONNAIRE

PAD Demographic and Clinical History Questionnaire

1. What is your age?_____
2. What is your gender? Male / Female
3. What is your race? (Please circle below)
   Black or African American / White / American Indian or Alaska Native / Asian / Native
   Hawaiian / Other Pacific Islander
4. What is your ethnicity? Hispanic or Latino / Non Hispanic or Latino
5. What is your marital status? Single / Married / Divorced / Widowed / Long term relationship
6. Do you have (circle all that apply):
   - Peripheral vascular disease? Yes / No
   - High Cholesterol? Yes / No
   - History of Smoking? Yes / No
   - Currently Smoking? Yes / No
   - High Blood Pressure? Yes / No
   - Diabetes? Yes No
   - Angina? Yes / No
   - Myocardial infarction Yes / No

7. Please list your current medications including the name of the medication, dose, and how often you take the medication:

_____
_____
_____
_____

8. Have you had surgery, balloon procedures or stents to any blood vessels other than your heart? Yes / No
   If yes, please describe which procedure(s):

_____
_____

_____

9. Have you had blockages in your coronary arteries? Yes / No
If yes, please describe blockage:

_____
_____
_____

APPENDIX B

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

PATIENT HEALTH QUESTIONNAIRE (PHQ-9)

NAME_____ DATE_____

Over the last 2 weeks, how often have you been bothered by any of the following probems?
(use "✓" to indicate your answer)

	Not at all	Several days	More than half the days	Nearly every day
1. Little interest or pleasure in doing things	0	1	2	3
2. Feeling down, depressed, or hopeless	0	1	2	3
3. Trouble falling or staying asleep, or sleeping too much	0	1	2	3
4. Feeling tired or having little energy	0	1	2	3
5. Poor appetite or overeating	0	1	2	3
6. Feeling bad about yourself – or that you are a failure or have let yourself or your family down	0	1	2	3
7. Trouble concentrating on things, such as reading the newspaper or watching television	0	1	2	3
8. Moving or speaking so slowly that other people could have noticed. Or the opposite – being so fidgety or restless that you have been moving around a lot more than usual	0	1	2	3
9. Thoughts that you would be better off dead, or of hurting yourself	0	1	2	3
	Add columns		+	+
(*Healthcare professional: For interpretation of TOTAL, Please refer to accompanying scoring card*)	TOTAL			

10. If you checked off any problems, how difficult have these problems made it for you to do your work, take care of things at home, or get along with other people?	Not difficult at all _____ Somewhat difficult _____ Very difficult _____ Extremely difficult _____

APPENDIX C

SAN DIEGO CLAUDICATION QUESTIONNAIRE (SDCQ)

Table 1. San Diego Claudication Questionnaire*

1. Do you get **pain, discomfort, or numbness** in your legs **when you walk**?

R	L	
1	1	.....Yes
2	2	.....No

2. Does this pain ever begin when you are **standing still** or **sitting**?

R	L	
1	1	.....Yes
2	2	.....No

3. In what part of the leg or buttock do you feel it?

	R	L	
(A) Includes calf/calves	1	1	.....Yes
	2	2	.....No
(B) Includes thigh/thighs	1	1	.....Yes
	2	2	.....No
(C) Includes buttock/buttocks	1	1	.....Yes
	2	2	.....No

4. Do you get it when you **walk uphill or hurry?**

R	L	
1	1	.....Yes
2	2	.....No
3	3	.....Never walk uphill or hurry

5. Do you get it if you walk at an **ordinary pace** on the level?

R	L	
1	1	.....Yes
2	2	.....No

6. Does the pain ever **disappear** while you are **still walking**?

R	L	
1	1	.....Yes
2	2	.....No

7. **What do you do** if you get this pain while you are walking?

R	L	
1	1	.....Stop or slow down
2	2	.....Carry on

8. What happens to it if you **stand still**?

R	L	
1	1	.....Lessens or relieved
2	2	.....Unchanged

9. How **soon**?

R	L	
1	1	.....10 minutes or less
2	2	.....More than 10 minutes

**Coding: (1) no exertional leg symptoms: 1 = 2; (2) rest pain: 1 = 1 and 2 = 1; (3) non-Rose exertional leg symptoms: 1 = 1 and 2 = 2 and 3a = 2 and (3b = 1 or 3c = 1); alternatively, 1 = 1 and 2 = 2 and 3a = 2 and* not *Rose; and (4) Rose intermittent claudication: 1 = 1 and 2 = 2 and 3a = 1 and (4 = 1 or [4 = 3 and 5 = 1]) and 6 = 2 and 7 = 1 and 8 = 1 and 9 = 1.*

APPENDIX D

WALKING IMPAIRMENT QUESTIONNAIRE (WIQ)

Walking Impairment Questionnaire (WIQ)

Walking Impairment: These questions ask about the reasons why you are having difficulty walking. We would like to know how much difficulty you had walking during the past week. By difficulty, we mean how hard it was or how much physical effort it took to walk because of each of these problems.

Peripheral Arterial Disease (PAD) Specific Questions — **Degree of Difficulty**

		None	Slight	Some	Much	Very
Pain, aching or cramps in your calves or buttocks?	Right Leg	4	3	2	1	0
	Left leg	4	3	2	1	0
	Both Legs	4	3	2	1	0

Differential Diagnosis — **Degree of Difficulty**

	None	Slight	Some	Much	Very
1. Pain, stiffness or aching in your joints (ankles, knees or hips)?	4	3	2	1	0
2. Weakness in one or both of your legs?	4	3	2	1	0
3. Pain or discomfort in your chest?	4	3	2	1	0
4. Shortness of breath?	4	3	2	1	0
5. Heart palpitations?	4	3	2	1	0
6. Other problems (please list)	4	3	2	1	0

Walking Distance: Report the degree of physical difficulty that best describes how hard it was for you to walk on level ground without stopping to rest for each of the following distances during the last week.

Distance — **Degree of Difficulty**

	None	Slight	Some	Much	Very
1. Walking indoors such as around your home?	4	3	2	1	0
2. Walking 50 feet?	4	3	2	1	0
3. Walking 150 feet (1/2 block)?	4	3	2	1	0
4. Walking 300 feet (1 block)?	4	3	2	1	0
5. Walking 600 feet (2 blocks)?	4	3	2	1	0
6. Walking 900 feet (3 blocks)?	4	3	2	1	0
7. Walking 1500 feet (5 blocks)?					

Walking Speed: Report the degree of difficulty that best describes how hard it was for you to walk one city block on level ground at each of these speeds without stopping to rest during the last week.

Speed **Degree of Difficulty**

	None	Slight	Some	Much	Very
1. Walking one block slowly?	4	3	2	1	0
2. Walking one block at an average speed?	4	3	2	1	0
3. Walking one block quickly?	4	3	2	1	0
4. Walking or jogging one block?	4	3	2	1	0

Stair Climbing: For each of these questions, report the degree of physical difficulty that best describes how hard it was for you to climb stairs without stopping to rest during the past week.

Stairs **Degree of Difficulty**

	None	Slight	Some	Much	Very
1. Climbing one flight of stairs?	4	3	2	1	0
2. Climbing two flights of stairs?	4	3	2	1	0
3. Climbing three flights of stairs?	4	3	2	1	0

APPENDIX E

VASCUQOL QUESTIONNAIRE

VascuQOL Questionnaire

Length of time	3 months ☐		6 months ☐		12 months ☐
since treatment:	2 years ☐		3 years ☐		4 years ☐

Instructions: These questions ask you how you have been affected by poor circulation to your legs over the last two weeks. **Please answer every question. Thank you.**

1. In the last two weeks **I have had pain in the leg (or foot) when walking** ……

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

2. In the last two weeks **I have been worried that I might injure my leg** ……

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

3. In the last two weeks **cold feet have given me** …….

1. A very great deal of discomfort or distress ☐ 1
2. A great deal of discomfort or distress ☐ 2
3. A good deal of discomfort or distress ☐ 3
4. A moderate amount of discomfort or distress ☐ 4
5. Some discomfort or distress ☐ 5
6. Very little discomfort or distress ☐ 6
7. No discomfort or distress ☐ 7

4. In the last two weeks, because of the poor circulation to my legs, **my ability to take exercise or to play any sports has been** …..

1. Totally limited, couldn't exercise at all ☐ 1
2. Extremely limited ☐ 2
3. Very limited ☐ 3
4. Moderately limited ☐ 4
5. A little limited ☐ 5
6. Only very slightly limited ☐ 6
7. Not at all limited ☐ 7

5. In the last two weeks **my legs have felt tired or weak** …..

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

6. In the last two weeks, because of the poor circulation to my legs, **I have been restricted in spending time with my friends or relatives** …..

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

7. In the last two weeks **I have had pain in the foot (or leg) after going to bed at night** …..

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

8. In the last two weeks **pins and needles or numbness in my leg (or foot)** have caused me ….

1. A very great deal of discomfort or distress ☐ 1
2. A great deal of discomfort or distress ☐ 2
3. A good deal of discomfort or distress ☐ 3
4. A moderate amount of discomfort or distress ☐ 4
5. Some discomfort or distress ☐ 5
6. Very little discomfort or distress ☐ 6
7. No discomfort or distress ☐ 7

9. In the last two weeks **the distance I can <u>walk has improved</u>** …..

1. Not at all (tick this if distance is unchanged or has decreased) ☐ 1
2. A little ☐ 2
3. Somewhat ☐ 3
4. Moderately ☐ 4
5. A good deal ☐ 5
6. A great deal ☐ 6
7. A very great deal ☐ 7

10. In the last two weeks, because of the poor circulation to my legs, **my ability to walk has been**

1. Totally limited, couldn't walk at all ☐ 1
2. Extremely limited ☐ 2
3. Very limited ☐ 3
4. Moderately limited ☐ 4
5. A little limited ☐ 5
6. Only very slightly limited ☐ 6
7. Not at all limited ☐ 7

11. In the last two weeks **being (or becoming) housebound has been a concern of mine** …..

1. A very great deal ☐ 1
2. A great deal ☐ 2
3. A good deal ☐ 3
4. Moderately ☐ 4
5. Somewhat ☐ 5
6. A little ☐ 6

7. Not at all ☐ 7

12. In the last two weeks **I have been concerned about having poor circulation to my legs** …..

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

13. In the last two weeks **I have had pain in the foot (or leg) when I am at rest** …..

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

14. In the last two weeks, because of the poor circulation to my legs**, my ability to climb stairs has been** …..

1. Totally limited, couldn't climb stairs at all ☐ 1
2. Extremely limited ☐ 2
3. Very limited ☐ 3
4. Moderately limited ☐ 4
5. A little limited ☐ 5
6. Only very slightly limited ☐ 6
7. Not at all limited ☐ 7

15. In the last two weeks, because of the poor circulation to my legs**, my ability to take part in social activities has been** …..

1. Totally limited, couldn't socialize at all ☐ 1
2. Extremely limited ☐ 2
3. Very limited ☐ 3

4. Moderately limited ☐ 4
5. A little limited ☐ 5
6. Only very slightly limited ☐ 6
7. Not at all limited ☐ 7

16. In the last two weeks, because of the poor circulation to my legs**, my ability to perform routine household work has been** …..

1. Totally limited, couldn't perform housework at all ☐ 1
2. Extremely limited ☐ 2
3. Very limited ☐ 3
4. Moderately limited ☐ 4
5. A little limited ☐ 5
6. Only very slightly limited ☐ 6
7. Not at all limited ☐ 7

17. In the last two weeks **ulcers in the leg (or foot) have given me pain or distress** …..

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time (tick this if you do not have leg ulcers) ☐ 7

18. Because of poor circulation to my legs, **the overall range of activities that I would have liked to do in the last two weeks has been** …..

1. Severely limited – most activities not done ☐ 1
2. Very limited ☐ 2
3. Moderately limited – several activities not done ☐ 3
4. Slightly limited ☐ 4
5. Very slightly limited – very few activities not done ☐ 5
6. Hardly limited at all ☐ 6
7. Not limited at all – have done all the activities that I wanted to ☐ 7

19. In the last two weeks **the poor circulation to the legs have made me feel frustrated** …..

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

20. In the last two weeks **when I do get pain in my leg (or foot) it has given me** ….

1. A very great deal of discomfort or distress ☐ 1
2. A great deal of discomfort or distress ☐ 2
3. A good deal of discomfort or distress ☐ 3
4. A moderate amount of discomfort or distress ☐ 4
5. Some discomfort or distress ☐ 5
6. Very little discomfort or distress ☐ 6
7. No discomfort or distress ☐ 7

21. In the last two weeks **I have felt guilty about relying on friends or relatives** …..

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

22. In the last two weeks, because of the poor circulation to my legs**, my ability to go shopping or carry bags has been** …..

1. Totally limited, couldn't go shopping at all ☐ 1
2. Extremely limited ☐ 2
3. Very limited ☐ 3
4. Moderately limited ☐ 4
5. A little limited ☐ 5
6. Only very slightly limited ☐ 6
7. Not at all limited ☐ 7

23. In the last two weeks **I have worried I might be in danger of losing a part of my leg or foot**

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

24. In the last two weeks **the distance I can walk <u>has become less</u>** …..

1. A very great deal ☐ 1
2. A great deal ☐ 2
3. A good deal ☐ 3
4. Moderately ☐ 4
5. Somewhat ☐ 5
6. A little ☐ 6
7. Not at all – tick if distance is unchanged or has increased ☐ 7

25. In the last two weeks **I have been depressed about the poor circulation to my legs** ….

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

APPENDIX F

THE PERIPHERAL ARTERIAL QUESTIONNAIRE

The Peripheral Arterial Questionnaire

The following questions refer to blockages in the arteries of your body, particularly your legs and how that might affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answer that best applies to you.

1. Blockages in the arteries, often referred to as **peripheral vascular disease**, affect different people in different ways. Some feel cramping or aching while others feel fatigue. Which leg (or buttock) causes you the most severe **discomfort, fatigue, pain, aching, or cramps**?

   the **Right** leg (buttock) ☐ the **Left** leg (buttock) ☐ **Both** are the same ☐ Neither ☐

2. Please review the list below and indicate how much limitation you have due to **your peripheral vascular disease** (discomfort, fatigue, pain, aching, or cramps in your calves (or buttocks) over the past 4 weeks.

Place an X in one box on each line

Activity	Extremely Limited	Quite a bit Limited	Moderately Limited	Slightly Limited	Not at all Limited	Limited for other reasons or did not do the activity
Walking around your home						
Walking 1-2 blocks on level ground						
Walking 1-2 blocks up a hill						
Walking 3-4 blocks on level ground						
Hurrying or jogging (as if to catch a bus)						
Vigorous work or exercise						

3. Compared with 4 weeks ago, have your symptoms of peripheral vascular disease (discomfort, fatigue, pain, aching, or cramps in your calves [or buttocks]) changed?

Much	Slightly	Not	Slightly	Much	I have had

Worse	Worse	Changed	Better	Better	no symptoms over the past 4 weeks

4. Over the past 4 weeks, how many times did you have discomfort, fatigue, pain, aching or cramps in your cramps (or buttocks)?

All of the time	Several times per day	At least once a day	3 or more times per week but not every day	1-2 times per week	Less than once a week	Never over the past 4 weeks

5. Over the past 4 weeks, how much has discomfort, fatigue, pain, aching or cramps in your calves (or buttocks) bothered you?

Extremely bothersome	Moderately bothersome	Somewhat bothersome	Slightly bothersome	Not at all bothersome	I've had no leg discomfort

6. Over the past 4 weeks, how often have you awakened with pain, aching, or cramps in your legs or feet?

Every night	3 or more times per week but not every night	1-2 times per week	Less than once a week	Never over the past 4 weeks

7. How satisfied are you that everything possible is being done to treat your peripheral vascular disease?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied

8. How satisfied are you with the explanations your doctor has given you about your peripheral vascular disease?

Not satisfied at	Mostly	Somewhat	Mostly	Completely

all	dissatisfied	satisfied	satisfied	satisfied

9. Overall, how satisfied are you with the current treatment of your peripheral vascular disease?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied

10. Over the past 4 weeks, how much has your peripheral vascular disease limited your enjoyment of life?

It has extremely limited my enjoyment of life	It has limited my enjoyment of life quite a bit	It has moderately limited my enjoyment of life	It has slightly limited my enjoyment of life	It has not limited my enjoyment of life at all

11. If you had to spend the rest of your life with your peripheral vascular disease the way it is right now, how would you feel about this?

Not at all satisfied	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied

12. Over the past 4 weeks, how often have you felt discouraged or down in the dumps because of your peripheral vascular disease?

I felt that way all of the time	I felt that way most of the time	I occasionally felt that way	I rarely felt that way	I never felt that way

13. How much does your peripheral vascular disease affect your lifestyle? Please indicate how your discomfort, fatigue, pain, aching, or cramps in your calves (or buttocks) may have limited your participation in the following activities over the past 4 weeks.

Please place an X in one box on each line

Activity	Severely limited	Limited quite a bit	Moderately limited	Slightly limited	Did not limit at	Does not apply or

					all	did not do for other reasons
Hobbies, recreational activities						
Visiting family or friends out of your home						
Working or doing household chores						

APPENDIX G

PAD ENDOVASCULAR TREATMENT QUESTIONNAIRE

Endovascular Treatment Questionnaire

1. What do you think are the benefits of endovascular treatment?

   _____
   _____
   _____
   _____

2. What were your major concerns after your endovascular procedure?

   _____
   _____
   _____
   _____

APPENDIX H

SURVEYMONKEY QUESTIONNAIRE FORMAT

Screening Questionnaire

*This survey should not take any longer than 20 minutes to complete

1. Have you been diagnosed with lower extremity peripheral arterial disease? This disease is associated with blockages in the arterial blood vessels of the lower legs.
   - o Yes
   - o No

*If no, thank you for your time. You are not eligible for this study. Please close the browser; If yes, continue with screening

2. Have you had any procedures on your legs for lower extremity peripheral arterial disease in the past 5 years that were not considered an emergency? Examples include balloon procedures or stents.
   - o Yes
   - o No

*If no, thank you for your time. You are not eligible for this study. Please close the browser; If yes, continue with screening

3. Do you read and speak English?
   - o Yes
   - o No

*If no, thank you for your time. You are not eligible for this study. Please close the browser; If yes, continue with screening

4. Have you been diagnosed with critical limb ischemia? This is a blockage in the arteries of the lower limbs that requires an immediate action to restore blood flow to that area. No action could result in gangrene or loss of the extremity.
   - o Yes
   - o No

*If yes, thank you for your time. You are not eligible for this study. Please close the browser; If no, continue with screening

5. Does your primary care provider recommend amputation (surgical removal of the limb) as a treatment option for your lower extremity peripheral arterial disease?
   - o Yes
   - o No

If yes, please describe which procedure(s):

_____
_____
_____

8. Have you had blockages in the blood vessels in your heart?
   - o Yes
   - o No

If yes, please describe blockage:

_____
_____
_____

9. Have you had surgery, balloon procedures or stents to the blood vessels in the arteries of your heart?

- o Yes
- o No

If yes, please describe which procedure(s):

_____
_____
_____

PAD Endovascular Treatment Questionnaire

1. Describe the benefits you have received from having your PAD treated with an endovascular procedure? What benefits of treatment were most important to you and why were these benefits important to you. Provide as much detail as possible.

_____
_____
_____
_____

2. Along with the benefits of treatment, patients with peripheral arterial disease sometimes report they have had concerns when undergoing treatment. What concerns did you experience while undergoing your endovascular procedure(s)? How did you deal with these concerns? Provide as much detail as possible.

_____
_____
_____
_____
_____

Walking Impairment Questionnaire (WIQ)

Walking Impairment: These questions ask about the reasons why you are having difficulty walking. We would like to know how much difficulty you had walking during the past week. By difficulty, we mean how hard it was or how much physical effort it took to walk because of each of these problems.

Please click on the number below that matches the degree of difficulty with each question.

Peripheral Arterial Disease (PAD) Specific Questions — **Degree of Difficulty**

		None	Slight	Some	Much	Very
Pain, aching or cramps in your calves or buttocks?	Right Leg	○ 4	○ 3	○ 2	○ 1	○ 0
	Left leg	○ 4	○ 3	○ 2	○ 1	○ 0
	Both Legs	○ 4	○ 3	○ 2	○ 1	○ 0

Differential Diagnosis — **Degree of Difficulty**

	Non	Slight	Some	Much	Very
1. Pain, stiffness or aching in your joints (ankles, knees or hips)?	○ 4	○ 3	○ 2	○ 1	○ 0
2. Weakness in one or both of your legs?	○ 4	○ 3	○ 2	○ 1	○ 0
3. Pain or discomfort in your chest?	○ 4	○ 3	○ 2	○ 1	○ 0
4. Shortness of breath?	○ 4	○ 3	○ 2	○ 1	○ 0
5. Heart palpitations?	○ 4	○ 3	○ 2	○ 1	○ 0
6. Other problems (please list)	○ 4	○ 3	○ 2	○ 1	○ 0

Walking Distance: Report the degree of physical difficulty that best describes how hard it was for you to walk on level ground without stopping to rest for each of the following distances during the last week.

Distance — **Degree of Difficulty**

	None	Slight	Some	Much	Very
1. Walking indoors such as around your home?	○ 4	○ 3	○ 2	○ 1	○ 0
2. Walking 50 feet?	○ 4	○ 3	○ 2	○ 1	○ 0
3. Walking 150 feet (1/2 block)?	○ 4	○ 3	○ 2	○ 1	○ 0
4. Walking 300 feet (1 block)?	○ 4	○ 3	○ 2	○ 1	○ 0
5. Walking 600 feet (2 blocks)?	○ 4	○ 3	○ 2	○ 1	○ 0
6. Walking 900 feet (3 blocks)?	○ 4	○ 3	○ 2	○ 1	○ 0

Walking Speed: Report the degree of difficulty that best describes how hard it was for you to walk one city block on level ground at each of these speeds without stopping to rest during the last week.

Speed — **Degree of Difficulty**

	Non	Slight	Some	Much	Very
1. Walking one block slowly?	○ 4	○ 3	○ 2	○ 1	○ 0
2. Walking one block at an average speed?	○ 4	○ 3	○ 2	○ 1	○ 0
3. Walking one block quickly?	○ 4	○ 3	○ 2	○ 1	○ 0
4. Walking or jogging one block?	○ 4	○ 3	○ 2	○ 1	○ 0

Stair Climbing: For each of these questions, report the degree of physical difficulty that best describes how hard it was for you to climb stairs without stopping to rest during the past week.

Stairs — **Degree of Difficulty**

	No	Slight	Some	Muc	Very
1. Climbing one flight of stairs?	○ 4	○ 3	○ 2	○ 1	○ 0
2. Climbing two flights of stairs?	○ 4	○ 3	○ 2	○ 1	○ 0
3. Climbing three flights of stairs?	○ 4	○ 3	○ 2	○ 1	○ 0

San Diego Claudication Questionnaire

Please click on the box which best describes your symptoms

1. Do you get pain, discomfort, or numbness in your legs when you walk?

Right leg
- o Yes
- o No

Left leg
- o Yes
- o No

2. Does this pain ever begin when you are standing still or sitting?

Right leg
- o Yes
- o No

Left leg
- o Yes
- o No

3. In what part of the leg or buttock to you feel it? (Click on choices below)

A. Includes Calf / Calves

Right leg
- o Yes
- o No

Left leg
- o Yes
- o No

B. Includes thigh / thighs

Right leg
- o Yes
- o No

Left leg
- o Yes
- o No

C. Includes buttock / buttocks

Right leg
- o Yes
- o No

Left leg
- o Yes
- o No

4. Do you get it when you walk uphill or hurry?

Right leg
- o Yes
- o No
- o Never walk uphill or hurry

Left leg
- Yes
- No
- Never walk uphill or hurry

5. Do you get it if you walk at an ordinary pace on the level?

Right leg
- Yes
- No

Left leg
- Yes
- No

6. Does the pain ever disappear while you are still walking?

Right leg
- Yes
- No

Left leg
- Yes
- No

7. What do you do if you get this pain while you are walking?

Right leg
- Stop
- Slow down

Left leg
- Stop
- Slow down

VascuQol Questionnaire

Length of time since treatment:

3 months ☐ 6 months ☐ 12 months ☐

2 years ☐ 3 years ☐ 4 years ☐ 5 years ☐

Instructions: These questions ask you how you have been affected by poor circulation to your legs over the last two weeks.

Please click on the box that most appropriately describes your symptoms. Thank you.

1. In the last two weeks **I have had pain in the leg (or foot) when walking** ……

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

2. In the last two weeks **I have been worried that I might injure my leg** ……

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

3. In the last two weeks **cold feet have given me** …….

8. A very great deal of discomfort or distress ☐ 1
9. A great deal of discomfort or distress ☐ 2
10. A good deal of discomfort or distress ☐ 3
11. A moderate amount of discomfort or distress ☐ 4
12. Some discomfort or distress ☐ 5
13. Very little discomfort or distress ☐ 6
14. No discomfort or distress ☐ 7

4. In the last two weeks, because of the poor circulation to my legs, **my ability to take exercise or to play any sports has been** …..

8. Totally limited, couldn't exercise at all ☐ 1
9. Extremely limited ☐ 2
10. Very limited ☐ 3
11. Moderately limited ☐ 4
12. A little limited ☐ 5
13. Only very slightly limited ☐ 6
14. Not at all limited ☐ 7

5. In the last two weeks **my legs have felt tired or weak** …..

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

6. In the last two weeks, because of the poor circulation to my legs, **I have been restricted in spending time with my friends or relatives** …..

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

7. In the last two weeks **I have had pain in the foot (or leg) after going to bed at night** …..

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6

7. None of the time ☐ 7

8. In the last two weeks **pins and needles or numbness in my leg (or foot)** have caused me ….

1. A very great deal of discomfort or distress ☐ 1
2. A great deal of discomfort or distress ☐ 2
3. A good deal of discomfort or distress ☐ 3
4. A moderate amount of discomfort or distress ☐ 4
5. Some discomfort or distress ☐ 5
6. Very little discomfort or distress ☐ 6
7. No discomfort or distress ☐ 7

9. In the last two weeks **the distance I can <u>walk has improved</u>** …..

1. Not at all (tick this if distance is unchanged or has decreased) ☐ 1
2. A little ☐ 2
3. Somewhat ☐ 3
4. Moderately ☐ 4
5. A good deal ☐ 5
6. A great deal ☐ 6
7. A very great deal ☐ 7

10. In the last two weeks, because of the poor circulation to my legs, **my ability to walk has been**

8. Totally limited, couldn't walk at all ☐ 1
9. Extremely limited ☐ 2
10. Very limited ☐ 3
11. Moderately limited ☐ 4
12. A little limited ☐ 5
13. Only very slightly limited ☐ 6
14. Not at all limited ☐ 7

11. In the last two weeks **being (or becoming) housebound has been a concern of mine** …..

8. A very great deal ☐ 1
9. A great deal ☐ 2
10. A good deal ☐ 3
11. Moderately ☐ 4
12. Somewhat ☐ 5
13. A little ☐ 6
14. Not at all ☐ 7

12. In the last two weeks **I have been concerned about having poor circulation to my legs** …..

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

13. In the last two weeks **I have had pain in the foot (or leg) when I am at rest** …..

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

14. In the last two weeks, because of the poor circulation to my legs**, my ability to climb stairs has been** …..

1. Totally limited, couldn't climb stairs at all ☐ 1
2. Extremely limited ☐ 2
3. Very limited ☐ 3
4. Moderately limited ☐ 4
5. A little limited ☐ 5
6. Only very slightly limited ☐ 6
7. Not at all limited ☐ 7

15. In the last two weeks, because of the poor circulation to my legs**, my ability to take part in social activities has been** …..

1. Totally limited, couldn't socialize at all ☐ 1
2. Extremely limited ☐ 2
3. Very limited ☐ 3
4. Moderately limited ☐ 4
5. A little limited ☐ 5
6. Only very slightly limited ☐ 6
7. Not at all limited ☐ 7

16. In the last two weeks, because of the poor circulation to my legs**, my ability to perform routine household work has been** …..

1. Totally limited, couldn't perform housework at all ☐ 1
2. Extremely limited ☐ 2
3. Very limited ☐ 3
4. Moderately limited ☐ 4
5. A little limited ☐ 5
6. Only very slightly limited ☐ 6
7. Not at all limited ☐ 7

17. In the last two weeks **ulcers in the leg (or foot) have given me pain or distress** …..

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time (tick this if you do not have leg ulcers) ☐ 7

18. Because of poor circulation to my legs, **the overall range of activities that I would have liked to do in the last two weeks has been** …..

1. Severely limited – most activities not done ☐ 1
2. Very limited ☐ 2
3. Moderately limited – several activities not done ☐ 3
4. Slightly limited ☐ 4
5. Very slightly limited – very few activities not done ☐ 5
6. Hardly limited at all ☐ 6
7. Not limited at all – have done all the activities that I wanted to ☐ 7

19. In the last two weeks **the poor circulation to the legs have made me feel frustrated** …..

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

20. In the last two weeks **when I do get pain in my leg (or foot) it has given me** ….

1. A very great deal of discomfort or distress ☐ 1
2. A great deal of discomfort or distress ☐ 2
3. A good deal of discomfort or distress ☐ 3
4. A moderate amount of discomfort or distress ☐ 4
5. Some discomfort or distress ☐ 5
6. Very little discomfort or distress ☐ 6
7. No discomfort or distress ☐ 7

21. In the last two weeks **I have felt guilty about relying on friends or relatives** …..

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

22. In the last two weeks, because of the poor circulation to my legs**, my ability to go shopping or carry bags has been** …..

1. Totally limited, couldn't go shopping at all ☐ 1
2. Extremely limited ☐ 2
3. Very limited ☐ 3
4. Moderately limited ☐ 4
5. A little limited ☐ 5
6. Only very slightly limited ☐ 6
7. Not at all limited ☐ 7

23. In the last two weeks **I have worried I might be in danger of losing a part of my leg or foot**

1. All of the time ☐ 1
2. Most of the time ☐ 2
3. A good bit of the time ☐ 3
4. Some of the time ☐ 4
5. A little of the time ☐ 5
6. Hardly any of the time ☐ 6
7. None of the time ☐ 7

24. In the last two weeks **the distance I can walk <u>has become less</u>** …..

1. A very great deal	☐ 1
2. A great deal	☐ 2
3. A good deal	☐ 3
4. Moderately	☐ 4
5. Somewhat	☐ 5
6. A little	☐ 6
7. Not at all – tick if distance is unchanged or has increased	☐ 7

25. In the last two weeks **I have been depressed about the poor circulation to my legs** ….

1. All of the time	☐ 1
2. Most of the time	☐ 2
3. A good bit of the time	☐ 3
4. Some of the time	☐ 4
5. A little of the time	☐ 5
6. Hardly any of the time	☐ 6
7. None of the time	☐ 7

The Peripheral Arterial Questionnaire

The following questions refer to blockages in the arteries of your body, particularly your legs, and how that might affect your life. Please read and complete the following questions. There are no right or wrong answers. Please mark the answer that best applies to you.

1. Blockages in the arteries, often referred to as **peripheral vascular disease**, affect different people in different ways. Some feel cramping or aching while others feel fatigue. Which leg (or buttock) causes you the most severe **discomfort, fatigue, pain, aching, or cramps**?

the **Right** leg (buttock)	the **Left** leg (buttock)	**Both** are the same	Neither
o	o	o	o

2. Please review the list below and indicate how much limitation you have due to **your peripheral vascular disease** (discomfort, fatigue, pain, aching, or cramps in your calves (or buttocks)) over the past 4 weeks.

Activity	Extremely limited	Quite a bit limited	Moderately limited	Slightly limited	Not at all limited	Limited for other reasons or did not do the activity
Walking around your home						
Walking 1-2 blocks on level ground						
Walking 1-2 blocks up a hill						
Walking 3-4 blocks on level ground						
Hurrying or jogging (as if to catch a bus)						

Vigorous work or exercise						

3. Compared to 4 weeks ago, have your symptoms of peripheral vascular disease (discomfort, fatigue, pain, aching, or cramps in your calves [or buttocks]) changed?
   My symptoms have become…

Much worse	Slightly worse	Not changed	Slightly better	Much better	I have had no symptoms over the past 4 weeks

4. Over the past 4 weeks, how many times did you have discomfort, fatigue, pain, aching, or cramps in your claves (or buttocks)?

All of the time	Several times a day	At least once a day	3 or more times per week but not every day	1-2 times per week	Less than once a week	Never over the past 4 weeks

5. Over the past 4 weeks, how much has discomfort, fatigue, pain, aching, or cramps in your claves (or buttocks) bothered you?
   It has been…

Extremely bothersome	Moderately bothersome	Somewhat bothersome	Slightly bothersome	Not at all bothersome	I've had no leg discomfort

6. Over the past 4 weeks, how often have you been awakened with pain, aching, or cramps in your legs or feet?

Every night	3 or more times per week but not every night	1-2 times per week	Less than once a week	Never over the past 4 weeks

7. How satisfied are you that everything possible is being done to treat your peripheral vascular disease?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied

8. How satisfied are you with the explanations your doctor has given you about your peripheral vascular disease?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied

9. Overall, how satisfied are you with the current treatment of your peripheral vascular disease?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied

10. Over the past 4 weeks, how much has your peripheral vascular disease limited your enjoyment of life?

It has extremely limited my enjoyment of life	It has limited my enjoyment of life quite a bit	It has moderately limited my enjoyment of life	It has slightly limited my enjoyment of life	It has not limited my enjoyment of life at all

11. If you had to spend the rest of your life with your peripheral vascular disease the way it is right now, how would you feel about this?

Not satisfied at all	Mostly dissatisfied	Somewhat satisfied	Mostly satisfied	Completely satisfied

12. Over the past 4 weeks, how often have you felt discouraged or down in the dumps because of your peripheral vascular disease?

I felt that way all of the time	I felt that way most of the time	I occasionally felt that way	I rarely felt that way	I never felt that way

13. How much does your peripheral vascular disease affect your lifestyle? Please indicate how your discomfort, fatigue, pain, aching, or cramps in your calves (or buttocks) may have limited your participation in the following activities of the past 4 weeks.

Activity	Severely limited	Limited quite a bit	Moderately limited	Slightly limited	Did not limit at all	Does not apply or did not do for other reasons
Hobbies, recreational activities						
Visiting family or friends out of your home						
Working or doing household chores						

Patient Health Questionnaire (PHQ-9)

Over the last 2 weeks, how often have you been bothered by any of the following problems? Please click on the answer that best fits your situation.

1. Little interest or pleasure in doing things
   - o Not at all
   - o Several days
   - o More than half the days
   - o Nearly every day

2. Feeling down, depressed or hopeless
   - o Not at all
   - o Several days
   - o More than half the days
   - o Nearly every day

3. Trouble falling or staying asleep, or sleeping too much
   - o Not at all
   - o Several days
   - o More than half the days
   - o Nearly every day

4. Feeling tired or having little energy
   - o Not at all
   - o Several days
   - o More than half the days
   - o Nearly every day

5. Poor appetite or overeating
   - o Not at all
   - o Several days
   - o More than half the days
   - o Nearly every day

6. Feeling bad about yourself - or that you are a failure or have let yourself or your family down
   - o Not at all
   - o Several days
   - o More than half the days
   - o Nearly every day

7. Trouble concentrating on things, such as reading the newspaper or watching television
   - o Not at all
   - o Several days
   - o More than half the days
   - o Nearly every day

8. Moving or speaking so slowly that other people could have noticed. Or the opposite - being so fidgety or restless that you have been moving around a lot more than usual
   - o Not at all
   - o Several days

- o More than half the days
- o Nearly every day

9. Thoughts that you would be better off dead, or of hurting yourself
   - o Not at all
   - o Several days
   - o More than half the days
   - o Nearly every day

10. If you checked off *any problems*, how difficult have these problems made it for you to do your work, take care of things at home or get along with other people?
   - o Not difficult at all
   - o Somewhat difficult
   - o Very difficult
   - o Extremely difficult

Please describe any medications you are currently taking:

Cholesterol lowering medications (Examples include Lipitor, Altoprev, Mavacor, Crestor, Zocor)
- o Yes
- o No

If yes, please describe

_____
_____

Diuretics (such as thiazide, hydrochlorothiazide (HCTZ), etc.
- o Yes
- o No

If yes, please describe

_____
_____

Medications to lower blood pressure
- o Yes
- o No

If yes, please describe

_____
_____

Blood thinning medications (such as aspirin, clopidogrel (Plavix), warfarin (coumadin), etc)
- o Yes
- o No

If yes, please describe

_____
_____

Symptom relief medications (such as cilostazol (Pletal), pentoxifylline (Trental), etc.
- o Yes
- o No

If yes, please describe

_____
_____

Medications to control diabetes

- o Yes
- o No

If yes, please describe

_____
_____

Medications for depression

- o Yes
- o No

If yes, please describe

_____
_____

APPENDIX I

IRB APPROVAL

MERCER UNIVERSITY

Institutional Review Board
For Research Involving Human Subjects

Tuesday, February 14, 2017

Ms. Serena Gramling
3001 mercer university drive
Georgia Baptist College of Nursing
atlanta, GA 30341

RE: A mixed methods study of the symptom experience of patients following endovascular treatment for lower extremity peripheral arterial disease (H1701027)

Dear Ms. Gramling:

On behalf of Mercer University's Institutional Review Board for Human Subjects Research, your application submitted on 30-Jan-2017 for the above referenced protocol was reviewed in accordance with Federal Regulations 21 CFR 56.110(b) and 45 CFR 46.110(b) (for expedited review) and was approved under category(ies) 7 per 63 FR 60364.

Your application was approved for one year of study on 14-Feb-2017. The protocol expires on . If the study continues beyond one year, it must be re-evaluated by the IRB Committee.

Item(s) Approved:
The purpose of this mixed methods study is to explore the symptom experience of patients with peripheral arterial disease following endovascular treatment including perceptions of treatment benefit. Use of Facebook and online survey.

NOTE: Please report to the committee when the protocol is initiated. Report to the Committee immediately any changes in the protocol or consent form and **ALL** accidents, injuries, and serious or unexpected adverse events that occur to your subjects as a result of this study.

We at the IRB and the Office of Research Compliance are dedicated to providing the best service to our research community. As one of our investigators, we value your feedback and ask that you please take a moment to complete our Satisfaction Survey and help us to improve the quality of our service.

It has been a pleasure working with you and we wish you much success with your project! If you need any further assistance, please feel free to contact our office.

Respectfully,

Ava Chambliss-Richardson, M.Ed., CIP, CIM.
Associate Director of Human Research Protection Programs (HRPP)
Member
Institutional Review Board

"Mercer University has adopted and agrees to conduct its clinical research studies in accordance with the International Conference on Harmonization's (ICH) Guidelines for Good Clinical Practice."