DECISIONAL CONFLICT IN PERIPHERAL ARTERIAL DISEASE: ASSOCIATION WITH TREATMENT CHOICE AND HEALTH STATUS

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DECISIONAL CONFLICT IN PERIPHERAL ARTERIAL DISEASE:

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ABSTRACT

Background: Symptom relief in peripheral arterial disease (PAD) can be obtained by invasive options such as endovascular stenting as well as exercise, and PAD medications. Each of these options have their own risks and benefits. A lack of knowledge about treatment options, risks and benefits, and how these matter to the patient, as well as a lack of support relating to treatment decisions can result in decisional conflict. We aimed to (1) document decisional conflict in patients facing PAD treatment decisions; (2) examine site variability in decisional conflict; and (3) examine whether decisional conflict is associated with PAD treatment strategy and 1-year health status outcomes.

Methods: The PORTRAIT study is an observational prospective study that enrolled patients with new or an exacerbation of PAD symptoms from 16 PAD specialty clinics in the US, the Netherlands, and Australia. Patients were interviewed before they underwent PAD treatments to document their socio-economic background and their health status (Peripheral Artery Questionnaire – PAQ). Medical history was abstracted from the medical records. At 3 months, treatment information and decisional conflict (yes/no – 4-item SURE instrument) information was collected from the patient. One-year follow-up health status information was collected by phone interview. Median odds ratios were calculated to quantify the level of site

variability. A multivariable logistic regression model was constructed to examine the association between decisional conflict and primary PAD treatment strategy (invasive vs. non-invasive). A multivariable linear regression model was built to examine the association between decisional conflict and 1-year PAQ summary scores, while adjusting for baseline PAQ summary scores.

Results: The unadjusted median odds ratio (MOR) for site variability was 2.01 (95% CI 1.56-3.13; p<0.001), after adjusting for country, the MOR was 1.12 (95% CI 1.00-1.46; p=0.35). After adjustment for site and relevant patient covariates, decisional conflict was associated with lower odds of receiving invasive treatment (OR=0.58; 95% CI 0.34-1.00; p=0.050). Decisional conflict was also associated with lower 1-year health status gains for the PAQ summary score (adjusted B=-4.72; 95% CI -9.38;-0.06; p=0.047), even adjusting for primary PAD treatment strategy.

Conclusion: One in five patients facing PAD treatment decisions experience decisional conflict. While there is considerable variation for the occurrence of decisional conflict, it is more common among non-US countries. As compared with patients who do not experience decisional conflict, those reporting conflict are more often managed non-invasively and experience lesser 1-year health status gains, not entirely explained by the primary PAD treatment modality. Increasing knowledge and support for non-invasive PAD treatment options may be ways to reduce decisional conflict in PAD.

APPROVAL PAGE

The faculty listed below, appointed by the Dean of the School of Medicine have examined a thesis "Decisional Conflict in Peripheral Arterial Disease: Association with Treatment Choice and Health Status," presented by Jeremy Burton Provance, candidate for Master of Science degree, and certify that in their opinion it is worthy of acceptance.

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CHAPTER 1

INTRODUCTION

Peripheral artery disease (PAD) affects 8.5 million Americans—approximately one in 16 Americans over 40 years old.[1] Its prevalence increases with age, with rates as high as 20% among those over 80-years old.[2] Recent global estimates suggest that PAD has been on the rise in low- to middle-income as well as high-income countries.[3]

The pathophysiology of PAD is most often explained by atherosclerosis of the lower extremity arteries, restricting the blood flow in the leg arteries. If symptomatic, PAD causes pain in the lower extremities clinically referred to as claudication. Common risk factors include smoking, diabetes, older age, obesity, hypertension, hypercholesterolemia, and a family history of PAD.[4] Patients with PAD are known to be high risk for fatal and non-fatal cardiovascular events (such as myocardial infarction or stroke) with rates that are disproportionately high as compared with coronary and cerebrovascular disease.[5] Despite its high burden, it is well documented that PAD is under-recognized and undertreated.[6]

PAD is generally diagnosed when a patient first presents with mild claudication symptoms. The primary goals of PAD treatment are cardiovascular risk reduction and symptom relief. Patients should routinely be offered antiplatelet and statin therapy, and patients who smoke should be referred for smoking cessation counseling. As for the symptom management, PAD can be treated invasively through endovascular and surgical revascularization procedures but symptoms can also be managed through claudication medications and supervised or home-based exercise therapy.[7] Due to the availability of a myriad of treatment options with no clear gold standard identified and acceptable risks and benefits for more than one alternative strategy to obtain symptom relief in PAD, clinical

equipoise is present.[8] Care in these scenarios is sensitive to patients' needs, preferences and values.[9] Ideally, the choice of treatment and associated risks and benefits should align with a patient's individual preferences. When patients' preferences are not taken into account, and instead, provider or system factors may guide the treatment decision, there is a potential for unwanted variation and outcomes.[10] Shared decision-making (SDM) offers a useful framework to reduce undesired provider- or system-related variations in treatment allocation and can stimulate a more engaged and preference-sensitive decision-making process.[11]

SDM refers to an interaction between a patient and provider to achieve mutual treatment goals. The inclusion of SDM in the clinical setting allows patients to review evidence for available treatment options and empowers patients to make treatment decisions weighing the potential risks and benefits against their preferences.[12] One of the central goals of SDM is to allow patients to become more engaged in their interactions with the provider, both for those who typically take more passive roles and those who wish to take a more active role in their health care.[13]

The SDM process consists of simple actions patients and their care team can do when making shared clinical decisions.[14] This process can be seen in flow chart form in Figure 1. Moving from the spectrum of an uninformed patient to an informed one, the patient first must convene with their care team to promote the patient's support network and discuss the importance of examining options. Next, describing the relevant options is a critical piece to making the best decision. In the case of PAD, this would mean being presented with all possible treatments in the invasive to non-invasive spectrum and its associated risks and benefits. If a tool were implemented to help a patient weigh the risks and benefits of a treatment plan (a decision aid), this second step would be an ideal time to do so. Third, a

patient should discuss their personal values as they relate to their health and desired outcomes. The patient should understand the amount of risks and benefits are involved for each treatment and discuss how those ratios align with their health preferences. As a last step, the patient will complete the SDM process if they decide on a relevant treatment that matches their preference. If the SDM process is unsuccessful, the patient may experience a degree of decisional conflict about the treatment choice. Decisional conflict can result when a patient lacks knowledge about their choice, they are unaware of the choices available to them, they do not understand the benefits and risks associated with each choice, or they do not have the necessary support to make a decision.[15]

A Cochrane Review on decision-making aids found that implementation of clinical decision aids had immediate effects of increasing patient knowledge of treatment options, resulted in more accurate patient perception of treatment risks, and empowered patients to choose treatment options that are more aligned with their values.[12] The review also showed that decision aids reduced decision conflict, moved patients away from a passive role to more active roles in their decision-making, and decreased the inability to actually make decisions.

In addition to these near-term effects of better informed patients who make preference-based treatment decisions, mid-term effects (Figure 2) are that patients tend to choose safer, more cost-effective options that align with their personal values.[14] By choosing treatments that better align with patient values, long-term effects of more efficient usage of resources and overall improved outcomes are expected. In theory, the near-term, mid-term, long-term effect cycle will positively feed back into everyday clinical decision-making in the clinic preventing decisional conflict and promoting better outcomes, more treatment satisfaction, and better quality of life.[16] Besides positive health effects, SDM has significant economic

implications. When given the choice, patients tend to choose less invasive options, which are typically less expensive.[17]

It is unclear what the quality of the decision-making process is for patients with a new or an exacerbation of PAD. The Patient-centered Outcomes Related to Treatment practices in peripheral Arterial disease: Investigating Trajectories (PORTRAIT) study was specifically designed to collect prospective information about the quality of the medical decision process, the care that patients were assigned to, and subsequent outcomes in patients managed for their PAD in a specialty care setting. In prior work, we documented that up to 19% of PAD patients in the PORTRAIT study report a discordant experience between their desire to be involved in the decision-making process and the way the actual decision took place[18] and 21% of patients expressed having had experienced decision conflict over their decision-making for PAD treatment.[19] It is unknown, however, how these initial decision experiences vary across PAD specialty clinics and how they are linked to actual treatment choice and subsequent health status outcomes.

To address these gaps in knowledge, we aimed to 1) document the site variability for the occurrence of decisional conflict in patients seen at PAD specialty clinics; 2) examine the association between the occurrence of decision conflict in PAD treatment and the primary PAD treatment patients underwent following their evaluation at the clinic (invasive versus non-invasive) and, 3) document the association between decision conflict and 1-year changes in PAD specific health status outcomes. Specifically, we hypothesize that decision conflict varies considerably across sites and that it exists in patients undergoing invasive treatment options. We also hypothesize that decision conflict is associated with less health status gains as compared with those who do not experience decision conflict. This knowledge will inform

future studies in SDM for PAD treatment and will help design interventions to implement protocols of SDM that may have the potential to increase patient engagement and reduce decision conflict for PAD treatment decisions.

CHAPTER 2

METHODS

Study Design and Patients

The PORTRAIT study is a multi-centered, prospective, observational registry organized at 16 PAD specialty clinics in the United States of America (Figure 5), The Netherlands (Figure 6), and Australia (Figure 7). Inclusion and exclusion criteria are shown in Table 1.[20]

Patients were recruited if they presented with an abnormal ankle-brachial index (ABI) and new-onset or worsening claudication symptoms. Prior to receiving PAD treatment, patients were interviewed by trained data collectors to obtain information about sociodemographic factors, psychosocial characteristics, their health status, and shared decision-making preferences. Demographic, clinical, and treatment information was abstracted from patients' medical records. Follow-up health status data was collected through centralized telephone interviews at 3, 6 and 12 months after enrollment. Treatment and information about decision making was obtained at the 3 month follow-up. Therefore, any treatments recorded would have occurred between the baseline interview and the 3 month time point. Figure 3 describes the data collection process.

The PORTRAIT study was approved by the coordinating center St. Luke's Health System's internal review board in Kansas City, Missouri, USA, and by the local ethical committees at each enrolling site. Informed consent was obtained from all participants.

Measures

Decision conflict refers to the feeling that one has insufficient knowledge or comfort about a medical decision[21] and was screened for by the SURE Instrument (Table 2). This 4-item screener was developed in a Canadian and rural US population based on the Decisional Conflict Scale[22] and has shown to be a reliable screening tool in both French- and English-speaking populations.[15] The SURE tool has been validated against the Decisional Conflict Scale with at 94.1% (95% CI 78.9-99.0) sensitivity and 89.8% (95% CI 87.1-92.0) specificity for identifying decisional conflict.[23] The SURE instrument uses four yes or no questions to determine if decision conflict has occurred in a patient's medical decision-making process. A "Yes" answer is scored as 1 and a "No" answer as 0; a composite score of less than 4 is an indicator for decision conflict.

PAD Treatment Information was obtained from the 3-month patient interviews. All peripheral revascularization procedures were captured including lower-extremity percutaneous transluminal angioplasty (with or without stenting), bypass surgery, endarterectomy, and atherectomy. Information about referral and attendance of a supervised or home-based exercise program was also collected from this interview. This included collecting information about whether the patient took part in PAD-specific, unsupervised exercise therapy, PAD-specific, supervised exercise therapy, or non-PAD specific exercise therapy. Patients were asked about the frequency and duration of their participation, whether they were still participating, and the reasons for stopping if applicable. This information was used to describe patient adherence to exercise therapy.

PAD-Specific Health Status was measured by the Peripheral Artery Questionnaire (PAQ), a validated, 20-item health status instrument with the following dimensions: physical

limitation, symptoms (frequency, severity, change over time), quality of life, social function and treatment satisfaction.[24] A summary score can be calculated based on the physical limitation, symptom frequency/burden, social function, and quality of life domains. Each of these scales is scored along different Likert scales. Scores on each domain and the summary scale can be calculated using a standardized algorithm and range from 0-100 with higher scores representing better health status. The PAQ has good internal validity and test-retest reliability.[24]

Other Covariate Information included variables relevant to the patients and their PAD treatment. These variables included demographic information, such as age, sex, and race. It included socioeconomic factors such as education level and insurance status. Medical history and vital information were collected through medical chart abstractions. Information on the patient's PAD characteristics was collected including typical or atypical symptoms using the San Diego Claudication Questionnaire[25], ankle brachial index, Rutherford index[26], and the highest claudication location. Smoking status was assessed using questions based on BRFSS and Question Inventory on Tobacco[27], alcohol consumption using AUDIT-C[28], as well as psychosocial health using the ENRICHD social support inventory[29]. The patient's provider type and preferences for shared decision making were collected using the Deber Questionnaire[30]. Information about medications, dosage, and frequency were collected in addition to reasons for not taking medication using the 2010 Performance Measures[31] and medication adherence using Medication Discussion Questions[32].

Statistical Analysis

Based on the SURE instrument results, all participants were categorized into either the "Decision Conflict Present" or the "Decision Conflict Not Present" group. Patient characteristics, primary PAD treatment strategy, and baseline and 1-year health status scores were described and compared by the presence of decisional conflict. Student's t-test were used for continuous variables and Chi-square or Fisher's exact text for categorical variables, where appropriate. Normality was confirmed in continuous scores, and if needed, non-parametric options (Mann–Whitney U test) were used.

We examined site variability by calculating median odds ratios and constructing 95% confidence intervals around the median odds ratio. The median odds ratio is used to make comparisons for randomly selected participants from different groupings. In this case, between the different clinic sites. Median odds ratios are used in place of interpreting a random or fixed effect for site in a participant specific analysis. If the median odds ratio is one, there is no variation at the site level. A ratio greater than one represents significant between-site variation.[33]

A multivariable logistic regression model was created to examine the relationship between decision conflict and primary treatment choice. Covariates were sequentially entered in step-wise blocks to better understand which type of variables impacted the association between decisional conflict and treatment choice. The step-wise blocks were as follows: (1) decision conflict present or absent; (2) country, site, and provider specialty; (3) age, sex, and race (white versus not white); (4) marital status (not married versus married), education level (less than high school education versus high school education or greater), and insurance status (no insurance versus any form of insurance) (5) ankle brachial index, disease location

(proximal, distal, or both) and history of peripheral arterial disease (as classified by a previous peripheral vascular atherectomy, endarterectomy, bypass surgery, or angioplasty); (6): history of acute myocardial infarction, history of stroke, history of heart failure, smoking status, and diabetes; and (7): whether or not the patients' preferred role in decision making was passive or not passive.

For the logistic regression model, assumptions were tested prior to the analysis. Linearity of continuous covariates was assessed by analyzing the natural logarithmic transformation of these variables. No variables showed significant values, thus there were no linear relationships present. Data cases were all independent. Multicollinearity was assessed by analyzing correlation coefficients between variables. No correlations greater than 0.70 existed between variables. There were no outliers. Inclusion in the outcome variable was mutually exclusive and collectively exhaustive. Hosmer-Lemeshow analysis was not significant ($p = 0.715$).

A multivariable linear regression model was created to examine the association between decisional conflict and 1-year PAQ summary scores. Sequential adjustments were made for the following covariates, in step-wise blocks: (1) decision conflict present or absent; (2) country, site, provider specialty, and PAQ summary baseline scores; (3) age, sex, and race (as white versus not white); (4) marital status, education level, and insurance status; (5) ankle brachial index, disease location (proximal, distal, or both), and history of peripheral arterial disease; (6) history of acute myocardial infarction, history of stroke, history of heart failure, smoking status, and diabetes; (7): treatment as four levels (non-invasive, no exercise therapy; non-invasive, exercise therapy; invasive, non-exercise therapy; and invasive, exercise therapy); and (8): passive vs. a non-passive role preference for decision-making.

For the multivariable linear regression model, assumptions were tested prior to the analysis. No multicollinearity existed in the data. No correlations greater than 0.70 existed between variables. There was homoscedasticity of residuals. There was a generally normal distribution of errors as assessed by normality and P-P plots. Durbin-Watson (2.032) showed outcome independence. There was a linear relationship between covariates and outcomes.

Analyses were conducted with SPSS Software version 24 (IBM corporation, Armonk, New York, USA) and with SAS version 9.4 (SAS Institute, Cary, North Carolina, USA). All tests performed were two-tailed and p-values less than 0.05 were considered statistically significant. Complete case analyses were performed.

CHAPTER 3

RESULTS

A total of 3,637 patients were screened for the PORTRAIT study. Of these, 1,608 (44.3%) were found to be eligible and 1,275 (79.3%) consented to participate. For our analytic cohort, 166 patients were excluded due to missing scores on our primary variable of interest (decisional conflict), leaving 1,109 patients within the analyses after exclusion.

A total of 231 (20.8%) patients reported experiencing decisional conflict. The frequencies for each item of the SURE-instrument patients (Table 3) was in accordance with the number of items patients expressed decisional conflict over (Table 4). The item that patients felt most conflicted about was the 'risks and benefits of treatment' item, followed by the 'risks and benefits that matter most' item.

Table 6 shows an overview of patient characteristics by the experience of decisional conflict or no decisional conflict. Compared with those who did not experience decisional conflict, patients that felt conflicted about their treatment decision were more likely to be white, less likely to have obtained a high school education, but more often had insurance. They had a different localization of their symptoms were less likely to have had a history of peripheral vascular intervention. Patients with decisional conflict less often presented with risk factors such as dyslipidemia and hypertension, or a history of percutaneous coronary intervention or coronary artery bypass grafting, but presented more often with chronic back pain. Patients with decisional conflict also reported lower treatment satisfaction and social support scores. Patients who reported decisional conflict, were most often enrolled from the vascular surgery setting, and from the Netherlands and Australia. They also reported adopting a more passive role for their decision making, and experiencing more discordance

between their preferred role for their decision-making and how the actual decision-making occurred. More patients with decisional conflict were referred for exercise therapy, particularly unsupervised therapy.

Site variability was examined using median odds ratios and 95% confidence intervals (CI) shown in Table 5 and Figure 8. The overall, unadjusted median odds ratio (MOR) was 2.01 (95% CI 1.56-3.53, $p < 0.001$). This value was no longer statistically significant after adjusting for country 1.12 MOR (95% CI 1.00-1.46, $p = 0.35$).

The results of the logistic regression modeling are provided in **Error! Reference source not found.**. In step 1, the estimate for the association between decisional conflict and non-invasive treatment referral was OR= -0.49; 95% CI 0.36-1.03; $p = 0.07$. Throughout the sequential adjustment of covariates, the estimate remained robust. In the fully adjusted model (after adding block 7), decisional conflict remained significantly associated with a referral to a non-invasive treatment strategy (Odds Ratio [OR] = -0.54; 95% CI 0.34-1.00; $p = 0.050$. Full model results are depicted in Table 10.

An overview of the multivariable linear regression results is shown in **Error! Reference source not found.**. In the step 1, decisional conflict was significantly associated with smaller 1-year health status improvements as compared with those who did not experience decisional conflict: B= -4.77; 95% CI -9.51-(-0.03); p-value 0.049. In the fully adjusted model, the association persisted after block 7 was introduced (B = -4.72; 95% CI -9.38-(-0.06); $p = 0.047$).

CHAPTER 4

DISCUSSION

One in five patients in the PORTRAIT study reported experiencing decisional conflict with regards to their PAD treatment. Significant variability across PAD specialty clinics was observed for the occurrence of decisional conflict, mostly explained by country variations in decisional conflict. Patients that expressed decisional conflict vs. those who did not were more likely to be white, insured, and less affected by cardiovascular risk factors, but more burdened by chronic back pain. They were more often referred to non-invasive PAD treatment strategies as opposed to invasive revascularization treatments.

Having decisional conflict was also associated with less improvement in 1-year PAD-specific health status scores as compared with those who did not experience decisional conflict. While the association attenuated when adjusting for the primary treatment modality in the health status, initial explorations indicated that decisional conflict more often occurred among those receiving unstructured instructions for exercise therapy and that no clear indications for non-adherence issues were found among those expressing decisional conflict.

This is the first study that examines aspects of the decisional quality of PAD treatment decisions in a specialty care setting. There are several treatment options available to manage PAD symptoms, with each of these options having different trade-offs in terms of risk, durability and timeline of benefits. In fact, recent clinical trial evidence from the CLEVER study demonstrated that both endovascular stenting options and supervised exercise therapy offer durable symptom relief of the same magnitude in patients with aorto-illiac disease.[34]

It is therefore important that patients' treatment is matched to their preferences and that patients are set up for success to make the treatment choice that aligns with their goals and preferences. Patients would need to have adequate knowledge and support to have informed and engaged discussions about their treatment with their providers. Virtually no information about these aspects of the decision-making process has been described as it relates to PAD. As a substantial subgroup experiences conflict surrounding their PAD treatment choice. The experience of conflict seems to be associated with less successful outcomes in terms of patients' health status. This study has the potential to highlight aspects of the decision-making process that may be amenable to change and could lead to insights that may help improve the decision-making process and potentially also subsequent outcomes for PAD.

We observed significant variation across sites as to whether patients were experiencing decisional conflict. Most of this variability was explained by country differences. As was demonstrated in prior preliminary work, significant country differences exist in the occurrence of decisional conflict and in preferred roles with regards to patients' decision-making.[35] Patients from non-US countries tend to have a preference for adopting a more passive role in their decision-making process, and from literature, it is known that a less engaged role in this process is associated with the experience of more decisional conflict.[12] Importantly, shared decision-making interventions have been designed and tested in patients with cardiovascular disease to demonstrate that patients can be encouraged to move from passive roles to more engaged interaction styles with regards to their medical decision-making process.[36]

Given prior literature that demonstrated that patients who are more informed and engaged tend to choose less invasive options for their treatment,[37] we expected that decisional conflict would be associated with invasive treatment options. In contrast, we observed a conflict for patients who received a non-invasive management strategy for their PAD symptoms. When characterizing patients by decisional conflict, there were indications that decisional conflict seems to be present particularly among those with unsupervised forms of exercise therapy, and those who said they were not offered a supervised form of exercise therapy. Decisional conflict remained a key factor in PAD treatment even after adjusting for multiple levels of factors. It is likely that patients who underwent invasive procedures did not experience as much conflict since providers are mandated to educate their patients on the procedure(s), risks, benefits, and probable outcomes for each treatment. There is certainly an acceptable amount of infrastructure and support surrounding the more invasive, higher-risk procedures as opposed to conservative PAD management strategies.

When linking the experience of decisional conflict to 1-year health status changes, we could demonstrate that patients who experience decisional conflict, had less PAD-specific health status gains, as compared with those who did not experience decisional conflict. It is unclear whether this association can solely be explained by the expected gains of the treatment modalities to which patients were assigned. The CLEVER results would argue against this notion, and was able to demonstrate that the non-invasive treatment of PAD symptoms through supervised exercise therapy can be equally beneficial as compared with stenting.[8] Adjusting for treatment modality did not attenuate the association between decisional conflict and worse 1-year health status gains in our analyses. Another potential explanation that we considered was whether patients who experienced decisional conflict

were less adherent in terms of their exercise and medication recommendations. From our initial descriptive comparisons, we found no clear indications that patients who experienced decisional conflict were different in terms of their adherence behaviors. The degree to which sufficient time, detail, support was spent when giving instructions for the non-invasive management of patients' PAD symptoms and what referrals were made, could really be the key information that may further help understand the less optimal benefits obtained in patients' 1-year health status. Therefore, it may well be that decisional conflict may not be a driver for suboptimal quality of life outcomes but rather that it may be a marker for a lack of adequate information, support, and preparedness for patients who are being managed with non-invasive options. Further work should further explore this notion.

Efforts to reduce decisional conflict have mainly focused on decision aids designed to increase knowledge of clinical options, weigh risks and benefits, describe implications for outcomes, increase patient satisfaction, and outline financial burdens that may result.[38-42] Most of these interventions are designed within the context of the shared-decision making paradigm. The design of educational tools or decision aids that summarize the evidence as it relates to risks and benefits of PAD treatment strategies to relieve patients' symptoms will be an important next step when designing interventions that can increase knowledge, stimulate the engagement with their providers as it relates to the decision-making process for managing PAD symptoms. Important future work would develop and implement better structural solutions to offer non-invasive management strategies for PAD symptoms. Access to, reimbursement, and availability of supervised exercise programs is key to set patients up for success. In addition, as PAD is a chronic disease that needs to be managed through targeting complex risk factors, one can also imagine that multidisciplinary, behavioral disease

management programs would need to be designed and tested to facilitate the non-invasive management of this disease and to optimize patients' health status outcomes.

Our results should be interpreted against the following limitations: First, information on the primary treatment strategy was patient-reported, and potential misclassification may have occurred. As abstraction and adjudication efforts are underway, we will be able to reconcile our results using the medical record treatment information. Second, our study was observational and there are possible risks of residual confounding and biases related to the treatment selection process. Our results need to be validated in other cohorts, treatment effects need to be further explored by reducing the potential for bias (e.g. with propensity score methodology), and future randomized studies with a focus on reducing decisional conflict may help address these potential biases. Third, we did not complete a formal mediation or moderator analysis and our explorations into potential explanations of the observed associations should mainly be viewed as hypothesis generating. Fourth, decisional conflict scores may have been impacted by the timing of patients' pending intervention, and future work may need to incorporate the timing of the intervention or the treatment discussion when interpreting the decisional conflict scores. Finally, 1-year health status outcomes may also have been impacted by whether or not technical success occurred and whether or not patients received intermediate treatments between the 3-month and 1-year time- mark.

Shared decision-making shows promise to achieve better quality of life for patients, specifically demonstrated in a population of peripheral arterial disease patients in this study. By identifying areas where shared decision-making does not occur and the reasons why it does not occur, further work can be done to provide strategies for empowering patients to

make informed clinical decisions, which would hopefully result in better overall outcomes. By exchanging evidence for these metrics, it is possible for the creation of predictive models for use by teams of providers and patients and supports a value-based care model rather than one on performance.

TABLES AND FIGURES

Table 1. PORTRAIT Study Inclusion and Exclusion Criteria

Inclusion Criteria	Exclusion Criteria
• Age ≥ 18 years • New-onset or recent exacerbation of exertional leg symptoms, regardless of whether symptoms are typical or atypical (buttock, thigh, hip or calf pain, numbness or discomfort inhibiting the patient's ability to walk distances) • Ankle-brachial index = resting ankle-brachial index assessment ≤0.90 or drop in post-exercise ankle pressure ≥20mmHg	• Non-compressible ankle-brachial index (ABI ≥1.30) • Patient had a lower-limb revascularization procedure in the ipsilateral leg where the patient is currently having symptoms in the past year (atherectomy, endarterectomy, bypass surgery, angioplasty) • Patient presents with a current episode of critical limb ischemia (ischemic rest pain, ulceration or gangrene) (Fontaine III, IV, or Rutherford grade IV-VI) • Non-English speaking or non-Spanish speaking for US sites; Non-Dutch speaking for Dutch sites; Non-English speaking for Australian sites • Hearing impairment • Currently a prisoner • Patient previously enrolled in PORTRAIT study • Unable to provide written informed consent

Table 2. SURE Instrument Categories and Questions; Used to Determine the Presence or Absence of Decisional Conflict—A No Answer in Any Category Results in Decisional Conflict Presence

Acronym Category	Test Question
Sure of Myself	Do you feel sure about the best choice for you?
Understand Information	Do you know the benefits and risks of each option?
Risk-benefit Ratio	Are you clear about which benefits and risks matter most to you?
Encouragement	Do you have enough support and advice to make a choice?

Table 3. Number of Patients (%) in Agreement with Individual SURE Items.

SURE Question	Agreed (%)
Do you feel sure about the best choice for you? (3 months)	995 (89.7)
Do you know the benefits and risks of each option? (3 months)	963 (86.8)
Are you clear about which benefits and risks matter most to you? (3 months)	964 (86.9)
Do you have enough support and advice to make a choice? (3 months)	990 (89.3)

Table 4. Overview of the number of patients (%) by the number of items they expressed decisional conflict over in the SURE instrument at 3 Months.

Number of Items on the SURE Instrument Expressing Decisional Conflict	Patients (%)
0	878 (79.2)
1	87 (7.8)
2	55 (5.0)
3	29 (2.6)
4	60 (5.4)
SURE Test Decisional Conflict Present	231 (20.8)

Table 5. Median Odds Ratios Used to Assess Site Variability. Includes Number of Sites, Median Odds Ratios with 95% Confidence Intervals, and P-Values.

	Number of Sites	Median Odds Ratio (95% CI)	P-Value
Overall	15		
Unadjusted		2.01 (1.56, 3.13)	< 0.001
Adjusted for Country		1.12 (1.00, 1.46)	0.35
By Country			
United States	9	1.32 (1.00, 1.98)	0.06
The Netherlands	5	1.00 (1.00, 1.41)	0.99
Australia	1	N/A	N/A

Table 6. Socio-Demographic, Medical History, and Health Status Factors in Patients Stratified by Decision Conflict Present or Not-Present. Counts, Local Percentages, and P-Values.

	Decisional Conflict (N=231)	No Decisional Conflict (N=878)	P-Value
Demographics			
Age	67.5±9.1	67.5±9.4	0.96
Sex			0.23
Male	153 (66.2)	544 (62.0)	
Female	78 (33.8)	334 (38.0)	
Race: White/Caucasian	207 (89.6)	710 (80.9)	0.001
Married	131 (57.5)	520 (59.5)	0.58
Currently working for pay at baseline			0.22
No	183 (79.6)	655 (74.9)	
Yes, full-time	32 (13.9)	132 (15.1)	
Yes, part-time	15 (6.5)	87 (10.0)	
Socio-Economic Factors			
≥ High school education	117 (52.0)	634 (72.5)	<0.001
Insurance	210 (90.9)	653 (74.4)	<0.001
Avoid care due to cost at baseline	31 (13.5)	120 (13.8)	0.91
Finances at the end of the month at baseline			0.67
Some money left over	120 (54.5)	479 (55.8)	
Just enough to make ends meet	74 (33.6)	296 (34.5)	
Not enough to make ends meet	26 (11.8)	84 (9.8)	
Disease Characteristics			
Function in Symptomatic Leg			0.19
Right leg	50 (21.6)	223 (25.4)	
Left leg	66 (28.6)	204 (23.2)	
Both legs	115 (49.8)	451 (51.4)	
Function: Claudication	231 (100)	874 (99.5)	0.59
Function: Location of highest claudication			0.026
Buttock	48 (20.8)	142 (16.2)	
Hip	18 (7.8)	78 (8.9)	
Thigh	29 (12.6)	141 (16.1)	
Calf	109 (47.2)	454 (51.9)	
Foot	9 (3.9)	12 (1.4)	
Other	18 (7.8)	47 (5.4)	
			0.28

	Decisional Conflict (N=231)	No Decisional Conflict (N=878)	P-Value
Function: Rutherford category			
Mild claudication	59 (26)	183 (21.1)	
Moderate claudication	108 (47.6)	436 (50.2)	
Severe claudication	60 (26.4)	250 (28.8)	
Ankle brachial index	0.67±0.19	0.70±0.19	0.53
Lesion Site			0.95
Proximal	136 (58.8)	399 (45.4)	
Distal	16 (6.9)	46 (5.2)	
Pain free walking distance (meters)	136.0±184.7	120.7±105.2	0.35
Duration of pain			0.91
< 1 month	6 (3.2)	20 (2.6)	
1-6 months	57 (30.3)	223 (29.5)	
7-12 months	31 (16.5)	140 (18.5)	
> 12 months	94 (50.0)	373 (49.3)	
Symptom presentation			0.25
Typical	177 (84.3)	709 (87.3)	
Atypical	33 (15.7)	103 (12.7)	
Medical History—Vascular			
Amputation	3 (1.3)	9 (1.0)	0.72
Peripheral vascular intervention	49 (21.2)	255 (29.0)	0.017
Medical History—Other			
BMI	29.2±6.4	29.0±6.5	0.70
Mean arterial pressure	105.4±74.7	95.5±26.2	0.004
Atrial fibrillation	23 (10.0)	102 (11.6)	0.48
Congestive heart failure	20 (8.7)	81 (9.2)	0.79
Dyslipidemia	166 (71.9)	709 (80.8)	0.003
Hypertension	172 (74.5)	711 (81.0)	0.028
TIA/CVA	28 (12.1)	100 (11.4)	0.76
Prior MI	35 (15.2)	169 (19.2)	0.15
PCI/CABG	59 (25.5)	324 (36.9)	0.001
Prior pacemaker	7 (3.0)	24 (2.7)	0.81
Prior ICD	3 (1.3)	19 (2.2)	0.59
Smoking status			0.60
Never	25 (10.9)	91 (10.4)	
Former	114 (49.6)	467 (53.2)	
Current	91 (39.6)	319 (36.4)	
Erectile dysfunction	16 (6.9)	47 (5.4)	0.36
Chronic kidney disease	20 (8.7)	99 (11.3)	0.25
Chronic lung disease	39 (16.9)	151 (17.2)	0.91
Sleep apnea	17 (7.4)	75 (8.5)	0.56
Osteoarthritis (hip or knee)	18 (7.8)	82 (9.3)	0.46

	Decisional Conflict (N=231)	No Decisional Conflict (N=878)	P-Value
Chronic back pain	43 (18.6)	111 (12.6)	0.019
Alcohol consumption	90 (39.3)	295 (33.8)	0.12
Cancer	26 (11.3)	86 (9.8)	0.51
Depression requiring treatment	27 (11.7)	108 (12.3)	0.80
Diabetes	76 (32.9)	291 (33.1)	0.94
PAQ Health Status at Baseline			
Physical limitation	41.1±27.6	38.3±25.9	0.17
Symptom stability	41.3±22.1	44.3±21.0	0.07
Symptoms	42.2±23.1	45.0±22.4	0.09
Treatment satisfaction	78.7±22.0	84.7±20.3	<0.001
Quality of Life	50.6±26.5	51.1±25.6	0.79
Social limitation	63.5±30.3	63.9±29.8	0.85
Summary	49.3±22.4	49.8±21.2	0.78
ESSI Social Support Status at Baseline			
Social support score	21.0±5.4	22.4±4.3	<0.001
Low social support score	55 (24.0)	116 (13.3)	<0.001
Provider Characteristics			
Specialty			<0.001
Interventional cardiologist	53 (22.9)	394 (44.9)	
Cardiologist	17 (7.4)	100 (11.4)	
Vascular surgeon	150 (64.9)	315 (35.9)	
Vascular medicine specialist	4 (1.7)	50 (5.7)	
Physician assistant	0 (0.0)	1 (0.1)	
Nurse practitioner	0	2 (0.2)	
Other	7 (3.0)	16 (1.8)	
Country			<0.001
USA	78 (33.8)	590 (67.2)	
Netherlands	122 (52.8)	235 (26.8)	
Australia	31 (13.4)	53 (6.0)	
Decision-making			
Preferred role type at baseline			<0.001
Passive	112 (54.4)	347 (41.4)	
Shared/Autonomous	94 (45.6)	492 (58.6)	
PAD treatment: Who is responsible for making treatment decisions at 3-month time point			<0.001
Doctor alone	61 (27.0)	120 (13.9)	
Mostly the doctor	59 (26.1)	179 (20.7)	
Doctor and you equally	77 (34.1)	488 (56.4)	

	Decisional Conflict (N=231)	No Decisional Conflict (N=878)	P-Value
Mostly you	21 (9.3)	46 (5.3)	
You alone	8 (3.5)	33 (3.8)	
Actual decision-making discordance	46 (22.2)	127 (15.1)	0.013
Quality of Care Indicators Prior to Treatment			
Statin 2010 performance measure	189 (81.8)	726 (82.7)	0.76
Antiplatelet (ASA/Clopidogrel) 2010 performance measure	193/202 (86.9)	770/792 (90.0)	0.19
Smoking cessation 2010 performance measure	65/202 (69.1)	234/811 (77.7)	0.09
Supervised exercise program performance measure	90/107 (42.1)	168/217 (20.3)	<0.001
Participation in Exercise Therapy at 3 Month Interview			
Participated in Exercise Therapy Following Diagnosis	93 (40.2)	273 (31.0)	0.007
Type of Exercise Program			
PAD-specific, unsupervised	77 (33.3)	174 (19.8)	0.001
PAD-specific, supervised	9 (3.8)	36 (4.1)	0.24
Non-PAD specific	9 (3.8)	38 (4.3)	0.29
Still participating	68 (29.4)	188 (21.4)	0.91
Stopped or did not participate			
Not offered	70 (30.3)	218 (24.8)	0.004
Medical reasons	15 (6.4)	33 (3.7)	0.035
Prefer walking	55 (23.8)	377 (42.9)	2.0 E-6
Insurance reasons	5 (2.1)	13 (1.4)	0.36
Cost reasons	6 (2.5)	12 (1.3)	0.13
Scheduling reasons	4 (1.7)	8 (0.9)	0.26
No program available	4 (1.7)	11 (1.2)	0.50
Felt better	6 (2.5)	13 (1.4)	0.23
Felt worse	10 (4.3)	30 (3.4)	0.41
Side effect reasons	3 (1.2)	2 (0.2)	0.050
Completed program	2 (0.8)	6 (0.6)	1.00
Other reasons	24 (10.3)	96 (10.9)	0.80
Medication Adherence at Three Month Interview—Reason for Not Taking Medications			
Forgot to take	64 (27.7)	320 (36.4)	0.053
Have too many	3 (1.2)	10 (1.1)	0.71
Too confusing	0 (0.0)	6 (0.6)	0.39

	Decisional Conflict (N=231)	No Decisional Conflict (N=878)	P-Value
Cost too much	3 (1.2)	6 (0.6)	0.37
Copay is too high	1 (0.4)	1 (0.1)	0.31
Could not attain	5 (2.1)	22 (2.5)	1.00
Unwanted side-effects	7 (3.0)	18 (2.0)	0.16
Began feeling worse	5 (2.1)	7 (0.7)	0.033
Began feeling better	1 (0.4)	5 (0.5)	1.00
Fear the medication	1 (0.4)	3 (0.3)	1.00
Wanted natural remedies	0 (0.0)	1 (0.1)	1.00
Other reason	12 (5.1)	22 (2.5)	0.006

Abbreviations: SD, standard deviation; TIA, transient ischemic attack; AMI, Acute Myocardial Infarction; PCI, percutaneous coronary intervention; CABG, coronary artery bypass graft; BMI, body mass index; EP device, electrophysiologic device; ABI, ankle brachial index; PAD, peripheral arterial disease; BMS, bare metal stent; DEB, drug eluting balloon; DES drug eluting stent

Table 7. Treatment Strategy and PAQ Scoring for Decisional Conflict or No Decisional Conflict Categories. Counts, Local Percentages, and P-Values.

	Decisional Conflict (N=231)	No Decisional Conflict (N=878)	P-Value
Treatment in First Three Months			
Treatment strategy			<0.001
Invasive	27 (11.7)	196 (22.3)	
Non-invasive	204 (88.3)	682 (77.7)	
Endovascular treatment	24 (10.5) [3]	176 (20.4) [17]	<0.001
Surgical treatment	4 (1.8) [3]	25 (2.9) [17]	0.34
PAQ summary score			
Baseline	49.3±22.4 [1]	49.8±21.2 [0]	0.78
12 Month	67.1±27.2 [39]	71.8±24.7 [126]	0.022
PAQ Change (12 Month minus baseline)	16.21±25.0 [39]	21.61±23.9	0.006

Table 8. Analysis Covariates Included in Logistic Regression and Multivariate Linear Regression Models

Block	Covariates Included
1	Country, clinic site, provider specialty, and PAQ summary baseline scores (for multivariable linear regression only)
2	Age, sex, and race
3	Marital, education, and insurance statuses
4	Ankle brachial index, proximal versus distal disease, history of PAD
5	History of myocardial infarction, transient ischemic attack, cerebrovascular accident, coronary artery bypass graft, diabetes, and smoking status
6	Cross variable between exercise therapy and treatment type (for multivariable linear regression only)
7	Passive versus not passive preference

Table 9. Sequential Logistic Regression Results. Odds Ratios (OR) and 95% CI are listed for the association between decisional conflict and primary PAD treatment strategy by each block of variables entered into the model.

Decisional Conflict	OR	95% CI	P-Value
Block 1—adjusting for country, provider site, and provider specialty	0.61	0.36-1.03	0.07
Block 2—adjusting for age, sex, and race	0.61	0.36-1.04	0.07
Block 3—adjusting for marital, education, and insurance statuses	0.61	0.36-1.04	0.07
Block 4—adjusting for ABI, distal versus proximal disease, and history of PAD	0.60	0.35-1.03	0.07
Block 5—adjusting for history of MI, TIA, CVA, CABG, Diabetes, and smoking status	0.58	0.34-1.00	0.050
Block 6—adjusting for passive versus not passive preference	0.58	0.34-1.00	0.050

Abbreviations: ABI, ankle brachial index; PAD, peripheral artery disease; MI, myocardial infarction; TIA, transient ischemic attack; CVA, cerebrovascular accident; CABG, coronary artery bypass graft

Variables included in the analysis are shown in Table 8

Table 10. Sequential Logistic Regression Covariates. Odds Ratios (OR) and 95% CI are listed for the last step-wise block.

	OR	95% CI	P-Value
Clinic Location (Site)	1.06	1.01-1.11	0.016
Provider Specialty	0.88	0.66-1.17	0.37
Country	0.82	0.45-1.51	0.52
Decisional Conflict Present	0.58	0.34-1.00	0.050
Age	0.98	0.96-1.01	0.16
Race	1.71	0.90-3.24	0.10
Sex	0.59	0.37-0.94	0.025
Marital Status	0.99	0.86-1.12	0.83
Educational Status	1.06	0.65-1.72	0.83
Insurance Status	0.94	0.46-1.93	0.87
ABI	0.23	0.07-0.73	0.013
Distal versus proximal disease	1.57	0.81-3.04	0.18
History of PAD	1.80	1.07-3.06	0.028
History of MI	1.05	0.59-1.86	0.88
History of TIA	0.55	0.18-1.69	0.29
History of CVA	0.75	0.32-1.75	0.49
History of CABG	0.90	0.48-1.69	0.74
History of DM	1.27	0.80-2.03	0.31
Passive role versus not passive role	0.98	0.62-1.56	0.95

Abbreviations: TIA, transient ischemic attack; MI, Myocardial Infarction; CABG, coronary artery bypass graft; ABI, ankle brachial index; PAD, peripheral arterial disease
Variables included in the analysis are shown in Table 8

Table 11. Sequential Multivariable Linear Regression Results. Odds Ratios (OR) and 95% CI are listed for the association between decisional conflict and 12 month PAQ summary scores by each block of variables entered into the model.

Decisional Conflict	B	95% CI	P-Value
Block 1—adjusting for country, provider site, provider specialty, and PAQ baseline scores	-4.77	-9.51-(-0.03)	0.049
Block 2—adjusting for age, sex, and race	-5.74	-10.41-(-1.08)	0.016
Block 3—adjusting for marital, education, and insurance status	-5.70	-10.38-(-1.03)	0.017
Block 4—adjusting for ABI, distal versus proximal disease, and history of PAD	-5.68	-10.37-(-0.99)	0.018
Block 5—adjusting for history of MI, TIA, CVA, CABG, Diabetes, and smoking status	-5.55	-10.25-(-0.85)	0.021
Block 6—adjusting for cross variable between exercise type and treatment type	-4.68	-9.33-(-0.02)	0.049
Block 7—adjusting for passive versus not passive preference	-4.72	-9.38-(-0.06)	0.047

Abbreviations: PAQ, peripheral artery questionnaire; ABI, ankle brachial index; PAD, peripheral artery disease; MI, myocardial infarction; TIA, transient ischemic attack; CVA, cerebrovascular accident; CABG, coronary artery bypass graft
Variables included in the analysis are shown in Table 8

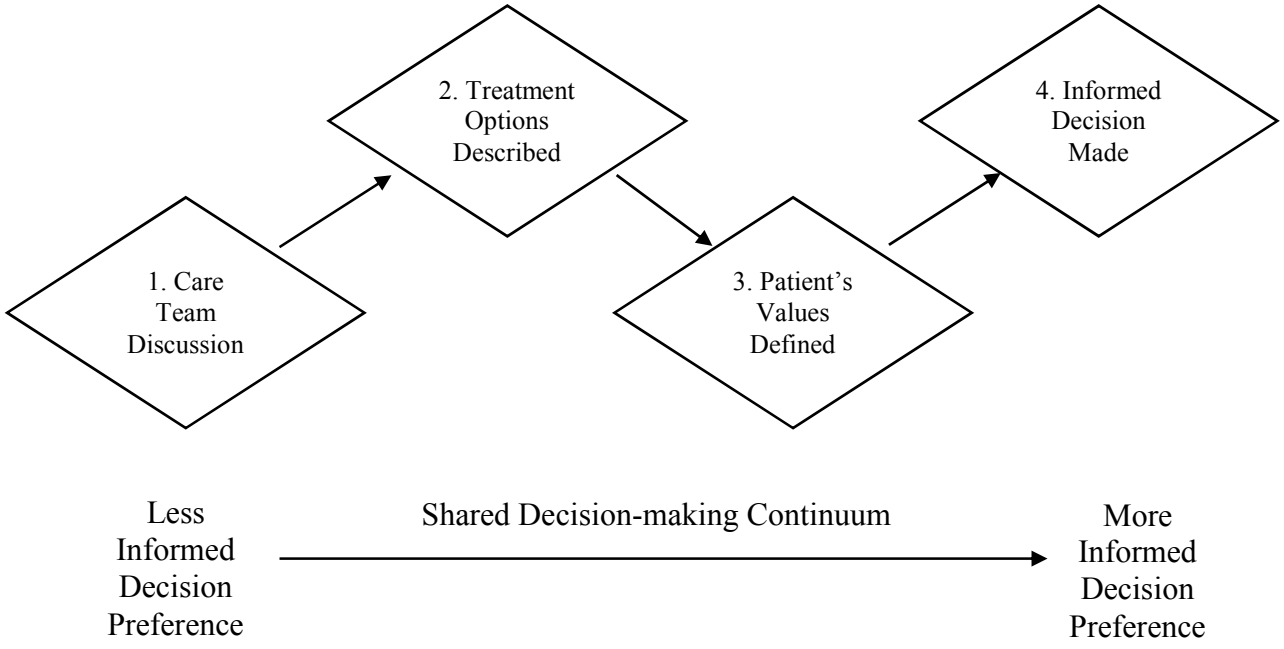

Figure 1. Shared Decision-making Continuum Adapted from Elwyn et al. 2014. Moving from Left to Right on the Continuum Through Each Numbered Action Steps Moves Towards More Informed Decision Preferences.

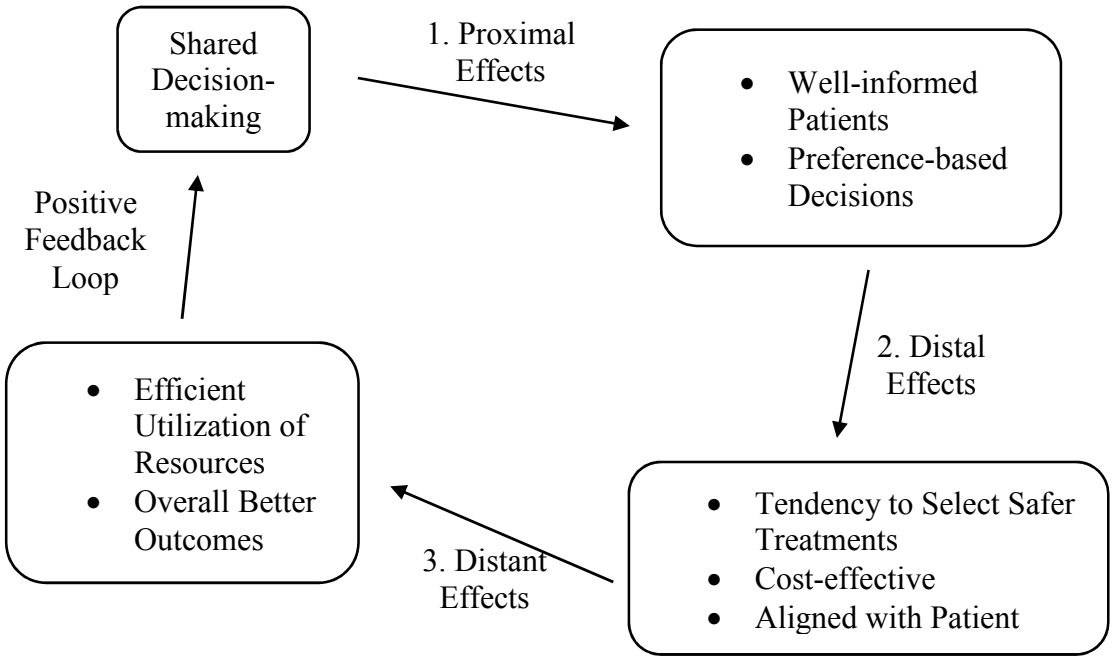

Figure 2. Long-term Effects of Shared Decision-making. Adapted from Elwyn et al. 2016. Moving Clockwise from the Top Left, the Effects (Proximal, Distal, and Distant) of Shared Decision Making are Outlined.

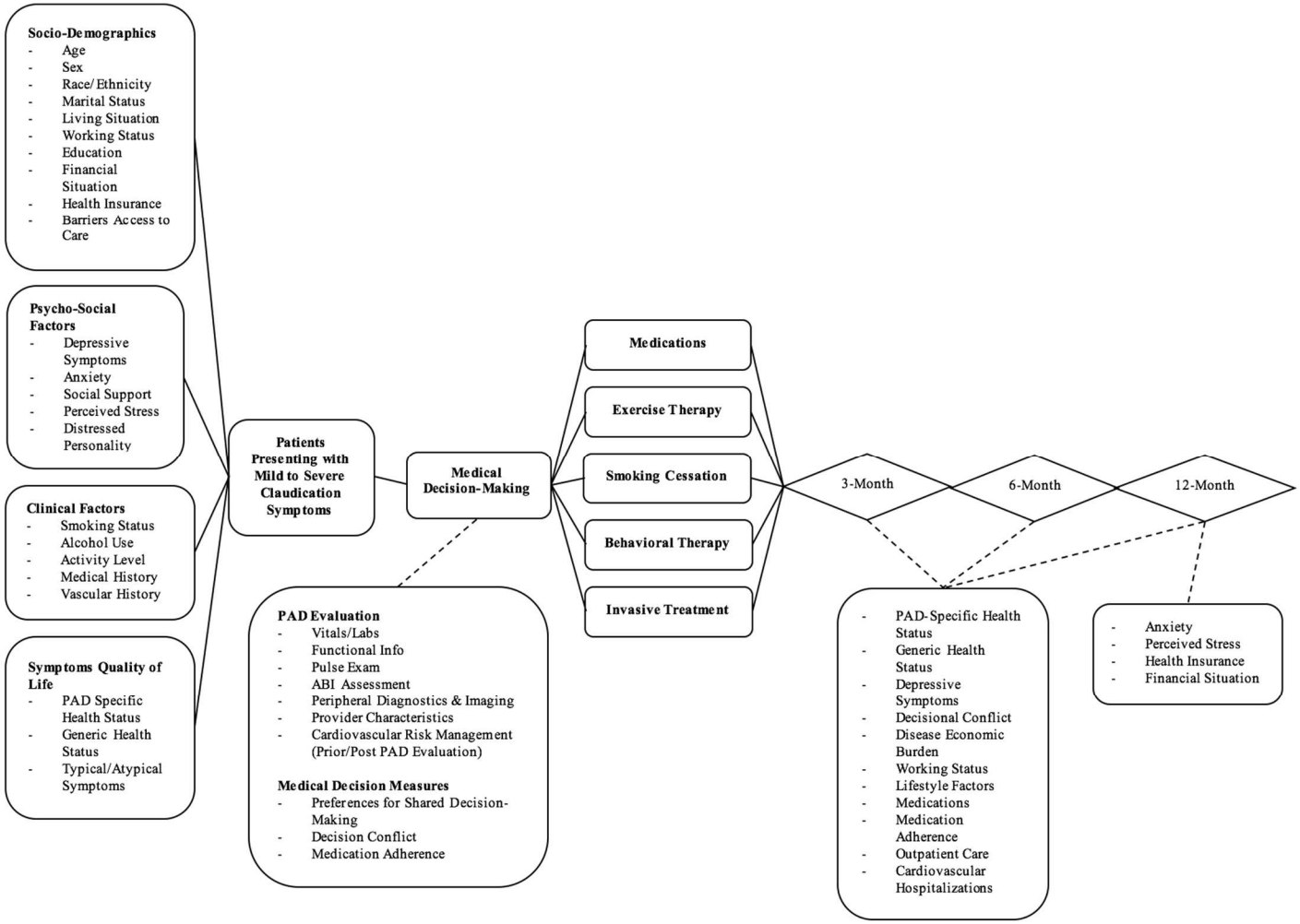

Figure 3. Case Report Form Data Collected as Potential Moderators and Mediators for Outcomes in New PAD Patients

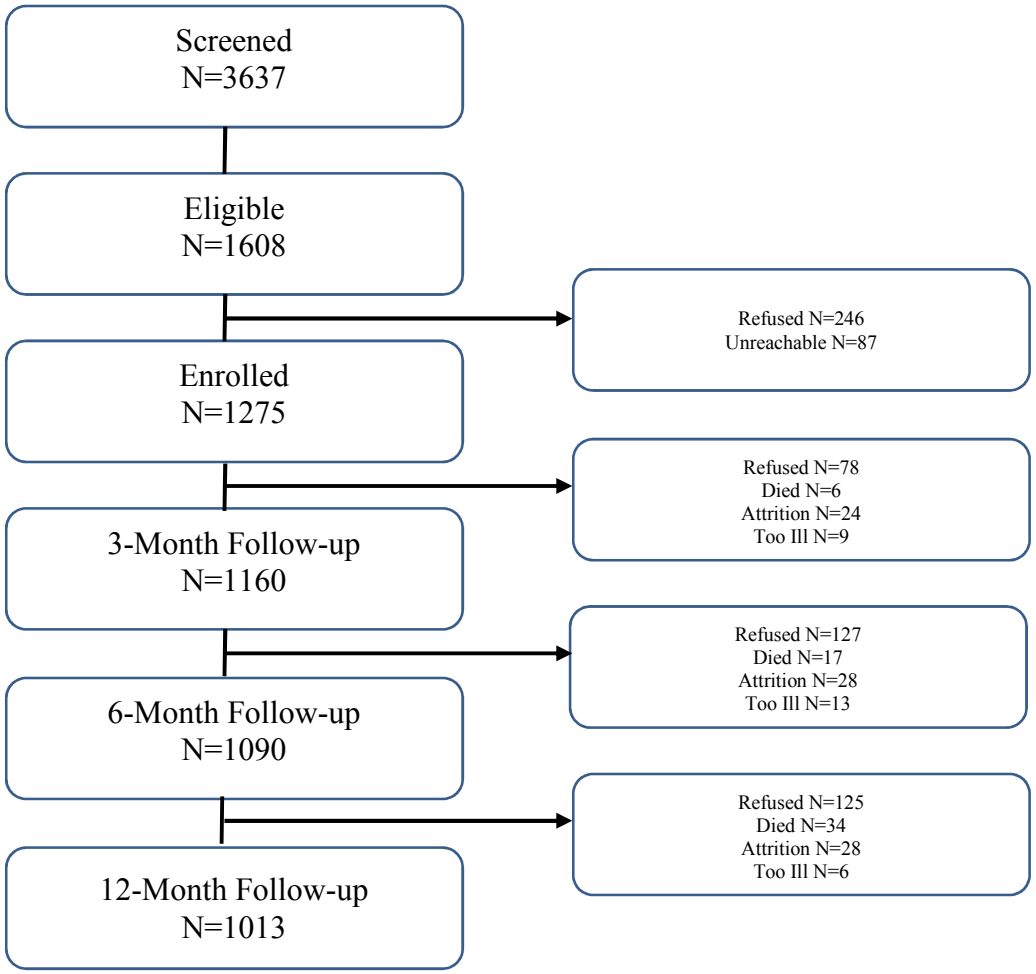

Figure 4. PORTRAIT Flowchart for Patients Screened, Eligible, Enrolled and Followed Including Attrition Due to Refusal, Unable to Reach, Death, General Attrition, and Being Too Ill

1. St. Luke's Mid-America Heart Institute, Kansas City, MO (David Safley, MD)
2. Truman Medical Center, Kansas City, MO (Mark Friedell, MD)
3. Ochsner St. Anna General Hospital, New Orleans, LA (Christopher White, MD)
4. Duke University Medical Center, Durham, NC (Manesh Patel, MD)
5. St. Joseph Mercy, Ann Arbor, MI (Herbert Aronow, MD)
6. Cleveland Clinic, Cleveland, OH (Medhi Shishehbor, MD)
7. Miriam Hospital, Providence, RI (Peter Soukas, MD)
8. Rhode Island HS, Providence, RI (Dawn Abbott, MD)
9. Yale New Haven Hospital, New Haven, CT (Carlos Mena, MD)
10. Bridgeport Hospital, Bridgeport, CT (Ed Tuohy, MD)

Figure 5. Map of the 10 PORTRAIT Enrollment Sites in the United States of America

1. St. Elisabeth Hospital, Tillburg (Patrick Vriens, MD, PhD)
2. Twee Steden Hospital, Tillburg (Marnix De Fijter, MD, PhD)
3. Zorgsaam Terneuzen (Alex Derom, MD)
4. Albert Schweitzer Hospital, Dordrecht (Rudolf Tutein-Nolthenius, MD, PhD)
5. St. Antonius Hospital, Nieuwegein (Jean-Paul de Vries, MD, PhD)

Figure 7. Map of the 5 PORTRAIT Enrollment Sites in The Netherlands

1. Queen Elisabeth Hospital, Adelaide (John Beltrame, MD, PhD; Rob Fitridge, MBBS MS FRACS)

Figure 6. Map of the 1 PORTRAIT Enrollment Site in Australia

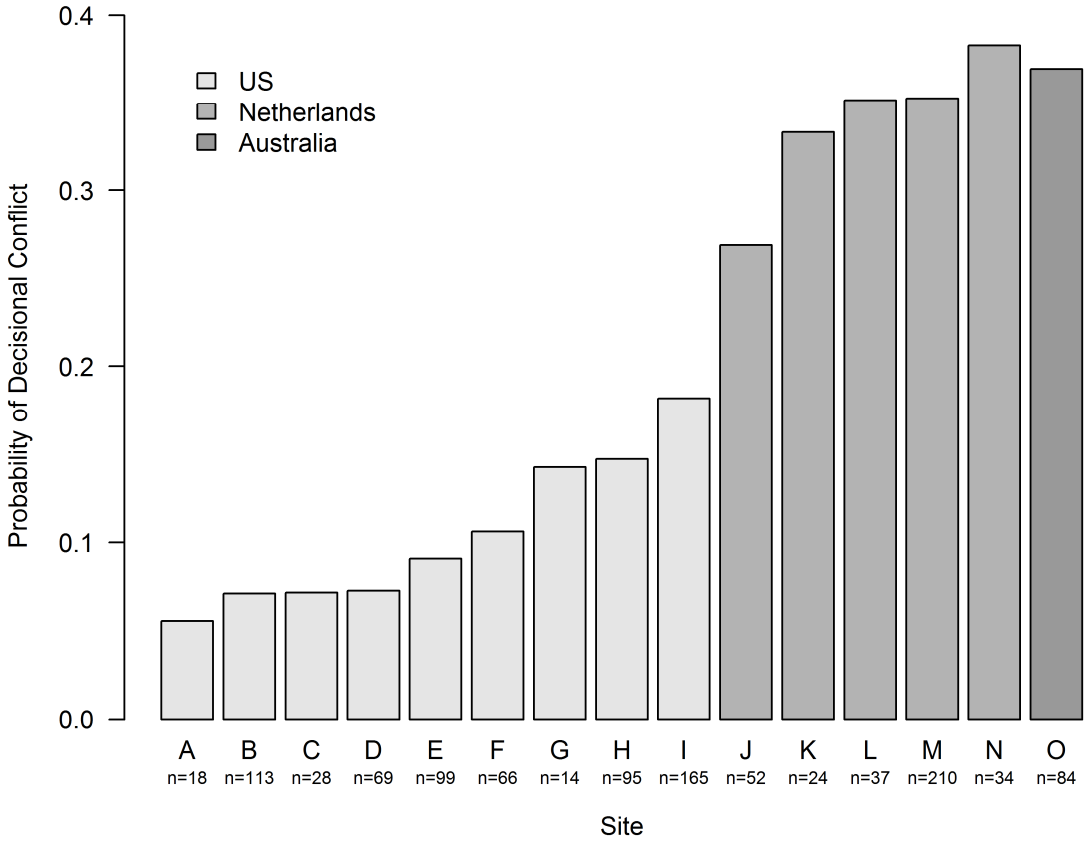

Figure 8. Ordered Median Odds Ratios for Site Variability as a Bar Graph. Probability of Decisional Conflict on the Y-Axis, Site on the X-Axis. Counts Associated with Site on the X-Axis are Number of Participants Included in Decisional Conflict Analysis per Site, Total N=1,109.

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VITA

Jeremy Burton Provance was born September 20, 1991 in Kansas City, Missouri. He was primarily educated in the Lee's Summit, Missouri public school system and graduated from Lee's Summit Senior High School in 2010. He received the Jewell Scholarship to attend William Jewell College in Liberty, Missouri and was awarded a Bachelor of Arts degree in Biology in 2014. He completed a senior research project studying fermentation science. He was the student body president during his third year of study and served on academic and civic advisory boards while attending William Jewell.

Upon graduation from undergrad, he worked in the brewing industry until December of 2015. In August 2015, he began a Master of Science in Bioinformatics degree through the Biomedical and Health Informatics Department at the University of Missouri-Kansas City School of Medicine. While at UMKC was inducted into Omicron Delta Kappa and served as secretary of the Graduate Student Council. In December 2015, he joined the Biomedical and Health Informatics Department working as a Software Analyst in the Center for Health Insights managing users for instances of REDCap and i2b2. Upon completion of his degree, Jeremy plans to continue working with the PORTRAIT data set in pursuit of a Ph.D. in Bioinformatics.

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