PORTRAIT Registry: *Patient-centered Outcomes Related to Treatment practices in peripheral Arterial disease: an International Trajectory*

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Specific Aim 1: Documentation of Treatment Practices in PADResearch focusing specifically on the compliance with PAD-specific guidelines across different outpatient clinics treating these patients, has not been prospectively evaluated. We will...

Ethical review	Approved WMO
Status	Pending
Health condition type	Other condition
Study type	Observational non invasive

Summary

ID

NL-OMON39963

Source
ToetsingOnline

Brief title
PORTRAIT Registry

Condition

- Other condition

Synonym
peripheral arterial disease, peripheral vascular disease

Health condition

perifeer arterieel vaatlijden

Research involving
Human

Sponsors and support

Primary sponsor: Universiteit van Tilburg
Source(s) of monetary or material Support: VENI 91611179,W.L. Gore & Associates, Inc. (Flagstaff, AZ)

Intervention

Keyword: Disparities., Patient-Centered Outcomes, Peripheral Arterial Disease, Quality of Care

Outcome measures

Primary outcome

Health Status as measured by the Peripheral Artery Questionnaire

Secondary outcome

Cardiovascular events

Study description

Background summary

Despite continuing efforts worldwide directed towards secondary prevention and optimization of treatment in cardiovascular disease, peripheral arterial disease (PAD) is still an under-recognized condition. PAD is a chronic atherosclerotic condition in which the blood flow of the arteries in the lower limbs is affected and prevalence increases up to 15-20% in the elderly. PAD patients have a disproportionate high disease burden compared with other atherosclerotic conditions. Approximately 1 in 3 patients experience a cardiovascular event 5 year following diagnosis, and survivors continue to have a compromised health status. Under-treatment of risk factors may partially explain this disproportionate high disease burden. How treatment variation is associated with patient-centered outcomes (health status, quality-of-life), and which vulnerable patient groups are most affected is unknown.

Through the development of a high-quality international PAD registry, we aim to evaluate the following priorities: (1) to further study the shortcomings in the way care for PAD is organized, (2) to identify high-risk subpopulations in

terms of their PAD care and outcomes, (3) to study the impact of identified differences in PAD care on health status, and (4) to relate differences in PAD care practices with outcomes.

These aims will be addressed in an observational prospective, multi-center registry enrolling patients from 15 international vascular outpatient clinics with new-onset PAD or exacerbation of previous PAD symptoms. Data collection will consist of 4 assessments: baseline, 3-, 6-, and 12 months.

Study objective

Specific Aim 1: Documentation of Treatment Practices in PAD

Research focusing specifically on the compliance with PAD-specific guidelines across different outpatient clinics treating these patients, has not been prospectively evaluated. We will therefore collect components needed to assess compliance with guideline-recommended care for PAD in an observational, multi-center, international PAD registry. The major advantage of information obtained from a registry refers to the fact that no large proportion of patients are excluded due to clinical considerations, and will more closely represent those patients seen in daily clinical practice, rather than the more *healthy* participants included in clinical trials.15 Guideline-recommended care (diagnostic methods, cardiovascular risk reduction, and revascularization treatments) will be documented from vascular outpatient settings.

Successfully accomplishing this aim would provide us with (1) detailed information on the availability and the extent to which guideline-recommended care in PAD is provided to patients, (2) insights into variations across international institutions, and (3) would identify significant gaps in the administration of PAD care to be targeted in future interventions.

Specific Aim 2: Identify Important PAD Subpopulations at Risk

Along with the data on PAD treatment patterns, relevant patient data that might influence both treatment and outcomes (e.g. socio-demographic, clinical, psychological, health habits) will be collected. These data will be necessary to document disparities in care in vulnerable subgroups of patients. Cardiovascular risk factors are disproportionately represented in minorities, and in patients who are vulnerable in terms of their socio-economic and psychological background. It is known from other patient populations that access and delivery of care is considerably compromised in these vulnerable groups. Research on disparities in PAD care and outcomes (including its socio-economic and psychological determinants) in vulnerable populations has not been well developed. Examples of under-documented areas include gender and racial disparities. For example, despite epidemiological findings indicating that women are at least equally afflicted with PAD as men, preliminary evidence

indicates that women are more likely to present with atypical symptoms, which could impact their chances on being diagnosed with PAD, and subsequently receiving appropriate treatment Furthermore, PAD prevalence rates are twice as high in non-Hispanic Blacks as compared with Caucasians, and Blacks and Hispanics have markedly higher amputation rates that Caucasians.

Given the scarcity of research on disparities in PAD care and outcomes, accomplishing this aim would further the field and would give us information as to how to prioritize future awareness, prevention, and treatment programs to eliminate these disparities.

Specific Aim 3: Quantify Outcomes, with a Focus on Health Status

Current PAD guidelines stress that treatment should be primarily aimed at improving patients* functioning and quality-of-life, and that patients* health status should be preferentially assessed with a disease-specific health status measure. Research on the impact of treatment variations in PAD on outcomes has thus far primarily focused on mortality and patency rates (i.e., the likelihood that a vessel remains free of occlusion). The association between treatment differences in PAD health status outcomes, however, has rarely been prospectively evaluated in real-world practice. Measuring PAD-specific health status in a prospective way with a disease-specific instrument would allow us to rigorously map the effects of differences in care practices on PAD patients* health status and to identify patients* at risk for having worse health status based on their demographic, socio-economic, or psychological characteristics. For this purpose, we will use the Peripheral Artery Questionnaire (PAQ), a validated, disease-specific measure that evaluates PAD patients* symptoms, physical function, social limitations, treatment satisfaction, and quality-of-life.

The rich information obtained by this aim would allow us to identify opportunities to improve patients* health status, and to prospectively quantify the health status benefits associated with guideline-recommended treatment.

Specific Aim 4: Study Treatment Practices and Association with Outcomes

Since guideline-based treatment practices will be specifically documented in specialized PAD outpatient settings, the current registry will give us the opportunity to provide much more detailed information on PAD-specific treatments than previously available in large cardiovascular registries. Information on the availability and access to supervised exercise programs, on opportunities to organize effective risk factor management, and on applied revascularization strategies would allow us to document treatment variation throughout practices and within PAD patients, and to evaluate the degree to which this variation compromises the ability to achieve guideline-based risk factor control targets and could explain variations in long-term outcomes (mortality and hospitalizations).

Due to the rich and detailed information on patients* clinical, demographic, socio-economic and psychological characteristics obtained by this registry, we would be able to study the impact of these characteristics on health outcomes. This is particularly important since prior studies on health outcomes in PAD were unable to adjust for these factors or to assess the extent to which these factors were associated with outcomes.

Study design

Methods

Population and Study Design
Consecutive patients consulting a vascular outpatient clinic with newly diagnosed symptomatic PAD or exacerbation of PAD symptoms will form the study population. Patients aged >=18 years, with a confirmed PAD diagnosis; supported by an abnormal resting or post-exercise ankle-brachial index (ABI<=0.90) will be included. Exclusion criteria include patients with a non-compressible ABI, critical leg ischemia, peripheral intervention procedure within the prior 12 months, patients that do not speak English patients who are hard of hearing, or are unable to provide informed consent (e.g. too ill). Inclusion will take place over a period of 2 year. The design is a prospective design with 4 assessments (baseline, 3 months, 6 months, 12 months), with the total study period being 12 months. Long-term follow-up (i.e., up to 5 years) will be included, but will be based on data retrieved from the patients* medical records only.

The novel character of this sampling refers to the fact that only patients with new-onset PAD will be included, whereas most registries used mixed populations of patients with prior PAD, with a history of revascularizations, or with different disease stages. This rigorous approach allows us to study a more homogeneous population providing results that are more easily interpretable and implementable in clinical practice.

Enrolling Centers and Patient Numbers
We will select 17 vascular outpatient clinics:(12 US and 5 non-US centers): Mid America Heart Institute Kansas City, MO; Minneapolis Heart Institute, Minneapolis, MN; Denver Veterans Affairs Medical Center, Denver, CO, Massachusetts General Hospital, Boston, MA, Duke University Medical Center, Durham, NC, Ochsner Health System, New Orleans, LA, CO, St. Joseph Mercy Health System - St. Joseph Mercy, Ann Arbor, Michigan, RI Hospital, Providence, RI, Miriam Hospital, Providence, RI, Prairie Heart Institute, Springfield, IL, and , Greenville Health System, Greenville, SC, Yale University, Connecticut, NY; 4 Dutch centers [St. Elisabeth Hospital/Tilburg University, Tilburg; Albert Schweitzer Hospital, Dordrecht]) and The Queen Elizabeth Hospital in Adelaide, Australia that have the infrastructure to collect the study data. Estimating that 75% of new patients will agree to participate in the registry, we expect to annually enroll 120 patients per center (note that RI Hospital and Miriam

Hospital will work together to enroll 120 patients), with a total of 1800 patients being enrolled. The Mid America Heart Institute and Tilburg University will serve as coordinating centers. Details of the research group and mentorship team are provided in Section 2c.

Data Elements and Data Collection Process
Data from each patient with new-onset PAD will be collected at baseline (on-site during the 1st visit for a diagnostic work-up or via telephone by a dedicated study coordinator). Follow-up information will be obtained by patient telephone interviews and by medical chart abstraction Interviews will use standardized and validated self-report instruments. Data entry will occur through a web-based data template accessible to all participating centers.

Study burden and risks

No risks are involved. Patients will only be asked to invest their time (20 minutes per interview at baseline, 3, 6, and 12 months follow-up)

Contacts

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Trial sites

Listed location countries

Netherlands

Eligibility criteria

Age
Adults (18-64 years)
Elderly (65 years and older)

Inclusion criteria

Patients aged >=18 years, with a confirmed PAD diagnosis; supported by an abnormal resting or post-exercise ankle-brachial index (ABI<=0.90) will be included.

Exclusion criteria

Exclusion criteria include patients with a non-compressible ABI, critical leg ischemia, peripheral intervention procedure within the prior 12 months, patients that do not speak English patients who are hard of hearing, or are unable to provide informed consent (e.g. too ill).

Study design

Design

Study type: Observational non invasive

Masking:	Open (masking not used)
Control:	Uncontrolled
Primary purpose:	Other

Recruitment

NL

Recruitment status:	Pending
Start date (anticipated):	18-07-2012
Enrollment:	600
Type:	Anticipated

Ethics review

Approved WMO Date:	19-03-2012
Application type:	First submission
Review commission:	METC Brabant (Tilburg)
Approved WMO Date:	10-06-2014
Application type:	Amendment
Review commission:	METC St Elisabeth Ziekenhuis (Tilburg)

Study registrations

Followed up by the following (possibly more current) registration

No registrations found.

Other (possibly less up-to-date) registrations in this register

No registrations found.

In other registers

Register	ID
ClinicalTrials.gov	NCT01419080
CCMO	NL41532.008.12