



Current status of patient-reported outcome measures in vascular surgery

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ABSTRACT

A previously published review focused on generic and disease-specific patient-reported outcome measures (PROMs) relevant to vascular surgery but limited to arterial conditions. The objective of this project was to identify all available PROMs relevant to diseases treated by vascular surgeons and to evaluate vascular surgeon perceptions, barriers to widespread implementation, and concerns regarding PROMs. We provide an overview of what a PROM is and how they are developed, and summarize currently available PROMs specific to vascular surgeons. We also report results from a survey of 78 Society for Vascular Surgery members serving on committees within the Policy and Advocacy Council addressing the barriers and facilitators to using PROMs in clinical practice. Finally, we report the qualitative results of two focus groups conducted to assess granular perceptions of PROMs and preparedness of vascular surgeons for widespread implementation of PROMs. These focus groups identified a lack of awareness of existing PROMs, knowledge of how PROMs are developed and validated, and clarity around how PROMs should be used by the clinician as main subthemes for barriers to PROM implementation in clinical practice. (*J Vasc Surg* 2021;74:1693-706.)

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The success of vascular surgery interventions is most commonly judged on objective measures defined by physicians. For example, the Society for Vascular Surgery (SVS) reporting standards for endovascular interventions to treat lower extremity peripheral artery disease (PAD) define key procedural outcomes including technical success, periprocedural complications, sustained hemodynamic improvement, patency, and freedom from repeat interventions.¹ Although objective measures of success are an important component of healthcare, patient perceptions of intervention outcomes are equally important. As a result, there has been increasing interest on the part of the healthcare community in patient-reported outcomes (PROs) for measuring treatment effectiveness and evaluating quality of care.

PROs are defined by the US Food and Drug Administration as “any report of the status of a patient’s (or person’s) health condition, health behavior, or experience with healthcare that comes directly from the patient, without interpretation of the patient’s response by a clinician or anyone else.”² PRO measures (PROMs) are the tools that are used to collect PROs and can measure outcomes in a variety of domains including quality of life, mood and physical function among others (Tables 1 through V provide examples of specific domains). The Centers for Medicare & Medicaid Services (CMS) recently defined PROMs as a high priority, suggesting that, “although patient reports of their health and experience with care are not the only outcomes that should be measured, they certainly are an important component.”⁸⁷

Table I. Peripheral arterial disease-related patient-reported outcomes measures (PROM)

PROM	Year	No. of items	Domains	Time to complete, min	Validated	Advantages	Disadvantages
CSI — Vascular ^{3,4}	2016	5	Symptoms	5	Yes	Assess specific symptoms, as opposed to global symptoms; designed and validated for assessment of outcomes to treatment	Limited testing in diverse populations; study was not designed for optimal evaluation of CSI sensitivity to change (responsiveness to change in patient's symptoms)
CLAU-S ⁵⁻⁷	1995	47	Everyday life, pain, effect on social activities, illness-specific fears, psychological impact	5	Yes	Strongly associated with objective measures of PAD severity	Functional assessment with limited use as global QOL tool
ECQ ^{8,9}	1992	6	Identification of claudication	Not reported	Yes	Tantamount to WHO/Rose but more specific	Not a true QOL assessment
FLeQKI ^{10,11}	2007	35	Comorbidity, effect on physical activities, effect on social activities, pain, psychological impact	Not reported	Yes	Correlate with SF-36	Only validated in German
Intermittent Claudication Questionnaire ¹²⁻¹⁵	2002	16	Pain, effect on physical activities, effect on social activities, psychological impact	3.7	No	Brief	Requires further validation
Peripheral Artery Disease Quality of Life Questionnaire ^{16,17}	2012	38	Social relationships and interactions, self-concept and feelings, symptoms, effect on physical activities, psychological impact, positive adaptation	<10	Yes	Demonstrates physical and emotional consequences of PAD on patient QOL	Limited testing in diverse populations, distinct age and race subgroups, and impact of intervention on disease progression
Peripheral Artery Questionnaire ^{18,19}	2004	20	Symptoms, change in symptoms, effect on physical activities, effect on social activities, treatment satisfaction, and overall QOL	Not reported	Yes	Holistic assessment of QOL and treatment effect	Less comprehensive than other PAD-specific QOL tools
Peripheral Artery Occlusive Disease 86-Item Questionnaire ^{12,13,16-23}	1995	86	Functional status, pain, general complaints, mood, anxiety, social life, evaluation of treatment for PAD	20	Yes	Extensive	Length limits adherence
PBI-PAD ^{24,25}	2018	12	Everyday life, working life, therapy, leisure time, body, psychological impact	Not reported	Yes	Calculates pre–post differences	Feasibility; 2 questionnaires over 3 months
Sickness Impact Profile—Intermittent Claudication ²⁶⁻³⁰	1975	12	Sleep and rest, home management, ambulation, mobility, social interaction and alertness, behavior	Not reported		Brief; uses simple scoring scheme	Largely bereft in clinical spaces
VascuQoL ³¹⁻³⁴	2001	25	Pain, symptoms, effect on physical activities, effect on social activities, psychological impact	9	Yes	Highlights PAD treatments effects on QOL	Relationship with functional status is lacking
VascuQoL-6 ³⁵	2014	6	Pain, symptoms, effect on physical activities, effect on social activities, psychological impact	1.4	Yes	Derived from VascuQoL but shorter	Limited comprehensiveness

Table I. Continued.

PROM	Year	No. of items	Domains	Time to complete, min	Validated	Advantages	Disadvantages
WHO/Rose Questionnaire ^{8,36,37}	1962	8	Identification of claudication	Not reported	Yes	Global utilization; endorsed by WHO	Not a true QOL assessment
Walking Impairment Questionnaire ^{34,38-41}	1990	22	Pain, distance, walking speed, and stair climbing	5	Yes	Strong correlation with objective measures of PAD severity	Functional tool only, not a global assessment of QOL

CLAU-S, Claudication Scale; *CSI*, Claudication Symptom Instrument; *ECQ*, Edinburgh Claudication Questionnaire; *PAD*, peripheral artery disease; *PBI-PAD*, Patient Benefit Index for Peripheral Arterial Disease; *QOL*, quality of life; *SF-36*, Short Form-36; *WHO*, World Health Organization.

ANATOMY OF A PROM

PROMs often take the form of a questionnaire that can either be completed by the patient on their own, or are administered to the patient by someone else.⁸⁸ Each item in the questionnaire is grouped into a “domain,” which represents a general category of assessment included in the PROM, such as pain, psychological impact, effect on social activities, and effect on physical activities (Tables I–V). Each PROM has a unique scoring mechanism that is relevant to the topic of the PROM.

Satisfaction versus health-related quality of life. Two broad categories of PROMs are health-related quality of life (HRQOL) measures, which can be general or disease specific; and satisfaction measures, which focus on the patient experience of receiving health care. HRQOL measures assess how a disease and its treatment affect the physical, psychologic, and/or social aspects of life.⁸⁹ HRQOL can be measured with objective assessments of functioning or health status (eg, frequency of pain) or more subjective evaluation of health (eg, extent to which pain hinders ability to engage in social activities).⁹⁰

Satisfaction differs from HRQOL in that it is entirely subjective. With respect to health care, patient satisfaction generally refers to the extent that the patient believes that high-quality health care was delivered.⁸⁹ Thus, satisfaction could potentially be defined differently by different people and satisfaction could be defined differently by the same person at different times.^{89,91} One of the most well-known satisfaction instruments is the Hospital Consumer Assessment of Healthcare Providers and Systems survey, which was developed by the CMS and the Agency for Healthcare Research and Quality. The Hospital Consumer Assessment of Healthcare Providers and Systems is administered to a random sample of patients discharged from a hospital on a monthly basis and addresses topics including nurse and doctor communication, and the cleanliness and quietness of the hospital environment.

PROM development. The US Food and Drug Administration dictates five steps in the development of a PROM.^{92,93} The first step is to develop an appropriate conceptual model. The specific concept of interest that the PROM aims to assess should be carefully defined along with boundaries for what is going to be assessed.

For example, if the objective is to assess pain, what are the components that will be measured (eg, intensity, quality, variability) and what are the components that are outside the scope of the proposed PROM (eg, treatment of the pain, effects of the pain on physical function and/or mental health)? Second, the conceptual framework is adjusted by gathering patient and stakeholder input, often in the form of focus groups and/or individual interviews. In the third step, a draft instrument is developed and assessed by administering the instrument to a diverse group of patients who would be in the target population for the PROM. These patients are interviewed individually after they complete the draft instrument to ensure readability and a uniform understanding of the items, as well as to examine whether additional domains should be included in the assessment.

The last two steps of PROM development are more relevant to HRQOL instruments than satisfaction instruments. The fourth step involves having large numbers (hundreds or thousands) of patients from diverse backgrounds and health circumstances complete the instrument and confirm that it measures what it intends to measure by comparing the responses with objective measures of health. The instrument’s sensitivity to change is also assessed by determining whether the instrument’s score changes appropriately with changes in the patient’s health status. Finally, the instrument undergoes translation and cultural adaptation and repeat of step four after those changes. The development of a PROM is meant to ensure its application to a broad range of patients regardless of race, sex, and ethnicity, although the extent to which this is true may vary by individual PROMs.

Objectives. A previously published review focused on generic and disease-specific PROMs relevant to vascular surgery but limited to arterial conditions.⁹⁴ The objective of this project was to identify all available PROMs relevant to diseases treated by vascular surgeons and to evaluate vascular surgeon perceptions, barriers to widespread implementation, and concerns regarding PROs.

OVERVIEW OF PROMS IN VASCULAR SURGERY

We performed a comprehensive literature search of PubMed using a series of search terms for PROMs (“patient reported outcomes” AND vascular AND surgery

NOT heart NOT breast). Ninety articles were identified, all of which were reviewed in a semi-structured manner by members of the SVS Performance Measures Committee. We identified 30 PROMs specific to vascular surgery disease processes.

PAD-specific PROMs. We identified 14 PROMs that address PAD (Table 1). Seven PROMs are general PAD instruments, and seven are specific to claudication. Of the general PAD instruments, the VascuQoL is widely used in research. The VascuQoL is composed of 25 questions assessing 5 QOL domains (pain, symptoms, activities, social impact, and emotional impact of PAD). It is brief and detects postintervention change in PAD severity better than generic HRQOL instruments.³¹ However, the VascuQoL is better used as an assessment of global QOL, as opposed to an instrument used for assessing functional status.^{32,33,94} The VascuQoL-6 is an abridged version of the VascuQoL and can be completed very quickly; however, its brevity calls into question the comprehensiveness of the instrument.^{35,94}

The Peripheral Artery Disease Quality of Life Questionnaire was validated using other established instruments that measured functional elements of PAD, including community-based walking ability in the Walking Impairment Questionnaire and health status in the 36-Item Short Form Health Survey (SF-36).¹⁶ The tool consists of 38 questions assessing 5 QOL domains (social relationships and interactions, self-concept and feelings, symptoms and limitations in physical functioning, fear and uncertainty, and positive adaptation) and can be completed in less than 10 minutes. However, the Peripheral Artery Disease Quality of Life Questionnaire has limited testing in some populations (Table 1).^{16,17} The Peripheral Artery Questionnaire is capable of assessing PAD-specific QOL, overall QOL, and treatment impacts on patient QOL. The questionnaire is comprised of 20 questions assessing 7 PAD-specific QOL domains (assessment of the most symptomatic leg, change in symptoms, physical limitation, social function, treatment satisfaction, and overall QOL); however, it is not the most comprehensive PAD-specific QOL instrument.^{18,94} The Peripheral Artery Occlusive Disease 86-Item Questionnaire has been used comprehensively to evaluate the QOL effects of combinations of pharmacologic and exercise on patients with PAD; however, the questionnaire takes approximately 20 minutes to complete, limiting its widespread use.^{12,13,16-20,94}

The Patient Benefit Index for Peripheral Arterial Disease (PBI-PAD) evaluates the severity of impairment of PAD-specific symptoms and sequelae.^{24,25} The PBI-PAD consists of two questionnaires—the Patient Needs Questionnaire and the Patient Benefit Questionnaire—with the former administered before treatment and the latter administered 3 months after treatment.²⁴ Although the PBI-PAD enables clinicians to calculate preprocedure and postprocedure differences, mitigating the likelihood

of response shift and recall bias, the questionnaire is administered over a time span of a few months, creating challenges with feasibility.²⁴

The FleQKI was originally used to measure QOL in patients with critical limb ischemia.^{10,11} Its validity and reliability are comparable to that of the SF-36; however, it is only validated in German.^{10,94}

Two claudication-specific instruments are used to identify patients with claudication: the World Health Organization (WHO)/Rose Questionnaire and the Edinburgh Claudication Questionnaire (ECQ). The WHO/Rose tool was developed in 1962 to assess patients with intermittent claudication and readapted in 1977 to satisfy requirements to become an official PRO.^{8,36} The questionnaire uses binomial scoring to identify individuals as either “claudicant” or “nonclaudicant.” Further adaptation allowed for differentiation of possible claudicants into grade 1 versus grade 2 claudication exhibiting increased sensitivity compared with its preadapted version.³⁷ Although the WHO/Rose questionnaire is supported by the WHO, it is not a true QOL tool.⁹⁴ The ECQ is used to identify patients with claudication in general populations^{8,25} and provides binary outcome analysis (claudicant vs nonclaudicant), of which claudicant can be further subdivided into definite claudicant and atypical claudicant. The ECQ is not intended to be used as a QOL measure.^{9,94}

Two surveys are useful for PAD severity but do not comprehensively measure QOL. The Claudication Scale (CLAU-S) exhibited strong associations with objective evaluators of PAD severity. However, while CLAU-S is useful for a quick functional assessment in claudicants, it is not a global assessment of QOL.^{5-7,94} Similarly, the Walking Impairment Questionnaire provides results that are strongly correlated with previously established, objective measures of PAD severity.³⁸⁻⁴⁰

The Intermittent Claudication Questionnaire assesses QOL in intermittent claudicants and highlights the effects of claudication on tasks such as performing errands.¹⁴ The Intermittent Claudication Questionnaire is easy to administer and has been validated in English and Turkish. However, it has only been studied in the context of exercise programs and requires validation through other PAD studies.^{12-15,94}

The Claudication Symptom Instrument was developed by the Comparative Effectiveness Research Translation Network Collaborative in 2010 to compare the response of symptoms to medical versus surgical treatment of claudication.³ A mean of the intensity score for the five evaluated symptoms is used to track symptoms over time or compare response to intervention.³ The Sickness Impact Profile—Intermittent Claudication is an abridged version of the Sickness Impact Profile, which has 11-fold more questions.²⁶⁻²⁸ Although the Sickness Impact Profile—Intermittent Claudication is a brief questionnaire and is easily scored, use of the disease-specific measures outside the context of the longer questionnaire requires further validation.^{29,30,94}

Table II. Aneurysm-related patient-reported outcomes measures (*PROM*)

<i>PROM</i>	Year	No. of items	Domains	Time to complete, minutes	Validated	Advantages	Disadvantages
AneurysmDQoL ⁴²⁻⁴⁵	2016	24	Physical symptoms, psychological symptoms, treatment satisfaction	Not reported	Yes	Provides most comprehensive assessments of fear of rupture, control, ability to forget about condition and size of aneurysm	Responsiveness to change not assessed
AneurysmSRQ ⁴²⁻⁴⁴	2016	44	Symptoms	Not reported	Yes	Provides most comprehensive assessments of fear of rupture, control, ability to forget about condition and size of aneurysm	Responsiveness to change not assessed
Aneurysm Treatment Satisfaction Questionnaire ⁴²⁻⁴⁴	2016	11	Monitoring/preintervention satisfaction, postoperative treatment satisfaction	Not reported	Yes	Assesses patient satisfaction presurgical and postsurgical intervention	Responsiveness to change not assessed
Consequences of Screening ^{46,47}	2018	62	Psychological, effects on social activities	Not reported	Yes	High content validity, responsiveness, and reliability	Limited testing in gender diverse populations — untested content validity and reliability

AneurysmDQoL, Aneurysm-Dependent Quality of Life; *AneurysmSRQ*, Aneurysm Symptom Rating Questionnaire.

Table III. Thoracic outlet syndrome (*TOS*)- related patient-reported outcomes measures (*PROM*)

<i>PROM</i>	Year	No. of items	Domains	Time to complete, minutes	Validated	Advantages	Disadvantages
CBSQ ^{38,48-50}	2007	14	Symptoms	Not reported	Yes	Useful in initial evaluation for <i>TOS</i>	Unclear ability to predict response to successful thoracic outlet decompression
DASH ^{51,52}	1996	30	Symptoms, effect on physical activities, effect on social activities	Not reported	Yes	Assesses problems associated with daily tasks	Length of questionnaire
Quick DASH ^{50,52-54}	2005	11	Symptoms, effect on physical activities, effect on social activities	Not reported	Yes	Same principles as DASH and less time	Not as comprehensive as DASH
NTOS ^{49,50,52,55,56}	2013	45	Symptoms, effect on physical activities, effect on social activities, pain	<20	No	Comprehensive, comprised of 3 tools (CBSQ, DASH, and 10-point scale for pain)	No clear advantage to this instrument over the CBSQ and DASH as individual measures

CBSQ, Cervical-Brachial Symptom Questionnaire; *DASH*, Disabilities of the Arm, Shoulder and Hand; *NTOS*, Neurogenic Thoracic Outlet Symptom Index.

Aortic aneurysm-specific PROMs. We identified four instruments specific to aortic aneurysms (Table II). The Aneurysm-Dependent Quality of Life (AneurysmDQoL)

questionnaire assesses condition-specific QOL for patients with abdominal aortic aneurysm (AAA).⁴²⁻⁴⁴ The AneurysmDQoL assesses effect of AAA-specific

Table IV. Venous disease-related patient-reported outcomes measures (PROM)

PROM	Year	No. of items	Domains	Time to complete, min	Validated	Advantages	Disadvantages
AVVQ ⁵⁷⁻⁶⁵	1993	13	Symptoms, effect on physical activities, use of compression, body image/appearance	<5	Yes	Varicose vein specific; can be used to compare different venous treatment options	Specificity often fails to assess side effects of venous interventions; more detailed evaluation of QOL when used in conjunction with the SF-36
CIVIQ20 ⁶⁶⁻⁶⁸	1996	20	Psychological, physical functioning, social functioning, and pain	Not reported	Yes	High content validity, reliability, internal consistency; high responsiveness by patients with self-administration	Limited assessment of mental impacts of having varicose veins
VCSS ^{69,70}	2000	10	Symptoms, physical examination	Not reported	Yes	Tracks change over time; especially after superficial venous surgery	Not designed to directly measure healthcare-related QOL
PRV ⁷¹⁻⁷³	2016	13	Symptoms, pain, body image/appearance	Not reported	Yes	Sensitive tool for diagnosing post-thrombotic syndrome	Text-based tool is not as accurate as the visually assisted tool
WSymQ ^{74,75}	2014	5	Symptoms	Not reported	Yes	Assesses patient experience of symptoms before and after the intervention	Limited comprehensiveness

AVVQ, Aberdeen Varicose Vein Questionnaire; CIVIQ20, Chronic Venous Insufficiency; PRV, patient-reported Villalta; QOL, quality of life; SF-36, Short Form 36; VCSS, Venous Clinical Severity Score.

symptoms on QoL and saliency of the symptoms.^{44,45} The Aneurysm Symptom Rating Questionnaire (AneurysmSRQ) assesses patient perception of the severity of AAA-specific symptoms.⁴²⁻⁴⁴ The AneurysmSRQ, in conjunction with the AneurysmDQoL, provides the most comprehensive assessments of fear of rupture, ability to forget about condition, and size of the aneurysm.⁴³ However, for both AneurysmSRQ and AneurysmDQoL, the responsiveness to change (ability to detect a change in clinical symptoms or condition over time) has yet to be assessed.⁴⁴

The Aneurysm Treatment Satisfaction Questionnaire addresses the lack of condition-specific PROM for patients with AAA.⁴²⁻⁴⁴ The instrument evaluates patient satisfaction, assessing multiple aspects of patient QOL and attitudes relating to medical treatment (eg, information, postoperative follow-up, convenience, results feedback, and side effects). The questionnaire assesses two domains. The first domain focuses on monitoring/preintervention aspects of AAA and is applicable to all patients. The second domain focuses on postintervention treatment and, therefore, is only relevant for patients who have undergone aneurysm repair. The Aneurysm Treatment Satisfaction Questionnaire assesses patient satisfaction presurgical and postsurgical intervention; however, its responsiveness to change has yet to be assessed.⁴⁴

The Consequences of Screening questionnaire is an AAA-specific tool for assessing the psychosocial effects of screening in asymptomatic patients.⁴⁶ The tool consists of two parts that assess 28 QOL dimensions ranging from anxiety, to uncertainty about the result of an ultrasound, to sexuality. Although the Consequences of Screening questionnaire has high content validity, responsiveness, and reliability among participants, the study was conducted using men and the content validity and reliability of this measure have not been tested among women.⁴⁶

Thoracic outlet syndrome-specific PROMs. There were four thoracic outlet syndrome (TOS) specific instruments identified (Table III). The Cervical-Brachial Symptom Questionnaire (CBSQ) has been used in a battery of PROMs for patients presenting for evaluation of TOS and measures functional upper extremity disturbances related to the performance of certain common physical activities.^{38,48,49} Although the CBSQ is useful in the initial evaluation for TOS, its ability to predict the response to successful thoracic outlet decompression is unclear.⁴⁹

The Disabilities of the Arm, Shoulder and Hand (DASH) questionnaire was jointly developed by the American Academy of Orthopedic Surgeons, the Council of Musculoskeletal Specialty Societies, and Toronto's Institute for Work and Health in 1996.⁵¹ The DASH assesses problems

Table V. Hemodialysis access, wounds and lymphedema-related patient-reported outcomes measures (PROM)

PROM	Year	No. of items	Domains	Time to complete, min	Validated	Advantages	Disadvantages
Hemodialysis access							
VAQ ^{76,77}	2008	17	Symptoms, body image/appearance, function, effect on physical activities, effect on social activities, and mood	Not reported	Yes	Assesses saliency of patient vascular access-related concerns	Initial study used limited testing in diverse populations
Wounds							
Wound QoL ⁷⁸⁻⁸⁰	2014	17	Everyday life, body, psyche	2.4	Yes	Validated for use in all patients with chronic wounds	Validated in English-speaking patients
Lymphedema							
Lymphedema of the Limbs Quality of Life—arm ⁸¹⁻⁸⁶	2010	22	Symptoms, body image/appearance, function, and mood	Not reported	Yes	Evaluated in several non-English languages	Construct validity and responsiveness not yet demonstrated
Lymphedema of the Limbs Quality of Life—leg ⁸¹⁻⁸⁶	2010	23	Symptoms, body image/appearance, function, and psychological	Not reported	Yes	Evaluated in several non-English languages	Construct validity and responsiveness not yet demonstrated

VAQ, Vascular Access Questionnaire.

associated with daily tasks.⁵² There are four optional items to assess QOL dimensions specific to workers, athletes, and musicians. However, its length brings into question the likelihood of patient adherence. The Quick DASH was developed as an abridged version of the DASH with same functionality as the original DASH.⁵²⁻⁵⁴ The Quick DASH exhibits greater precision in differentiating various intensities of disability; however, it is not as comprehensive as the original DASH.⁵⁴

The Neurogenic Thoracic Outlet Symptom (NTOS) Index is a composite score that combines the validated DASH and CBSQ with a 10-point visual analog scale for pain.^{49,52,55} Constituent tools are scored, and the final scores are transformed onto a scoring range from 0 to 100, with a higher score suggesting greater degrees of disability. Although the NTOS Index is highly comprehensive, no clear advantage has been identified for using the NTOS Index as opposed to the composite tools independently.⁵⁶

Venous-specific PROMs. We identified five PROs specific to venous disease (Table IV). The Aberdeen Varicose Vein Questionnaire (AVVQ) encompasses predominantly physical domains and social functioning aspects of QOL in patients with varicose veins.⁵⁷ The AVVQ was validated in a prospective study using the self-administered SF-36 in patients undergoing varicose vein

surgery.⁵⁸ The AVVQ has since been used in multiple randomized studies as a measure to compare different venous treatment options. Its specificity often fails to assess the side effects of venous interventions; however, when used in conjunction with the SF-36, the AVVQ provides a more detailed evaluation.⁵⁹⁻⁶⁵

The Chronic Venous Insufficiency (CIVIQ20) questionnaire identifies aspects of quality of life affected by venous insufficiency beyond physical discomfort,⁶⁶ including psychological, physical functioning, social functioning, and pain. The CIVIQ20 has high content validity, internal consistency, and reliability in clinical research projects. In addition, it can be self-administered and had high sensitivity to change over time (responsiveness). However, the CIVIQ20 questionnaire offers a less thorough assessment of mental impacts of having varicose veins.^{67,68}

The Venous Clinical Severity Score (VCSS) was developed by the American Venous Forum in 2000 as part of the three-part Venous Severity Score (VSS).⁶⁹ The VSS also includes the Venous Segmental Disease Score and the Venous Disability Score. The VCSS was developed to expand the CEAP classification by using a 0 to 3 scaling system for symptoms and findings that are progressive, measuring changes over short periods of time.⁶⁹ VCSS scores correlate with the extent of the diseases anatomically. Additionally, the validation study

illustrated the sensitivity of VCSS and VSS to changes after superficial venous surgery.⁷⁰ Although the VCSS and VSS are not technically PROs, because both instruments include a physical examination component, both are a reliable way of tracking changes over time and used as a measure for comparison in several randomized trials.⁷⁰

The patient-reported Villalta (PRV) scale was developed as an adaptation of the original Villalta scale, which is used to diagnose post-thrombotic syndrome.⁷¹ Although the Villalta scale requires a clinical visit to perform a physical examination of an affected limb, the PRV scale was developed as a self-reported tool to assess symptoms and signs of post-thrombotic symptoms. The PRV has been shown to have very good agreement with the original Villalta scale,⁷² and has been used to enable remote assessment of PTS in a recent large clinical study.⁷³

The VVSymQ Instrument assesses unpleasant symptoms of varicose veins.⁷⁴ The instrument is useful in assessing patient experience of varicose vein symptoms before and after the intervention; however, its brevity brings into question the comprehensiveness of the instrument.⁷⁵

Hemodialysis access-specific PROMs. The Vascular Access Questionnaire (VAQ) assesses patient perception and attitude surrounding vascular access-related issues⁷⁶ (Table V). The VAQ can be used to assess the saliency of patient vascular access-related concerns.^{76,77} However, the initial study outlining its development and clinical usefulness was limited, sampling only from a pool of Canadian dialysis patients within a single-payer health care system.⁷⁶

Wound-specific PROMs. The Wound-QoL instrument measures wound-related QOL in patients with chronic wounds of varying etiology (Table V). The Wound-QoL incorporates components of three different preexisting PRO surveys—the Freiburg Life quality Assessment for wounds, the Cardiff Wound Impact Schedule, and the Wurzberg Wound Score—and has been validated for use in all patients with chronic wounds.^{78,79} Compared with these preexisting instruments, the Wound-QoL also evaluates multiple dimensions of quality of life; it is validated in English and is shorter in length, decreasing the patient burden of responding and improving the chances of obtaining high-quality data.⁸⁰

Lymphedema-specific PROMs. The Lymphedema of the Limbs Quality of Life (LYMQOL) instrument is a lymphedema-specific instrument that has been adapted to both arm- and leg-specific lymphedema⁸¹ (Table V). The face and content validity for both Lymphedema of the Limbs Quality of Life have been demonstrated as well as for the four domains.⁸² The instrument has been evaluated in several non-English languages⁸³⁻⁸⁶; however, construct validity and responsiveness have yet to be demonstrated.⁸²

Selecting PROMs. Although recommendations for specific PROMs for vascular surgery patients are outside the scope of this review, there are some general considerations and resources to assist when deciding whether to start collecting PROs and how to select specific measures. The first consideration when selecting a specific measure is the intended use. For example, if the goal is to improve the diagnosis of patients with claudication, an instrument such as the ECQ would be most appropriate (Table I). Alternatively, if the goal is to assess change in symptoms over time in response to treatment, then a measure designed to assess symptom severity would be most appropriate (eg, the Claudication Symptom Instrument) (see Tables I–V for the advantages and disadvantages of specific measures). Additional criteria to consider are whether the measure is validated (see anatomy of a PROM) and whether it is appropriate for the patient population selected. For example, there are measures that are validated general measures for quality of life for assessing change across a diverse group of patients (SF-36) and those that are specific to a particular disease process (see Tables I–V). Measure item length and availability in multiple languages can also have significant implications for response rate and limit adequate sampling of a patient population. Finally, factors that influence feasibility of implementation should be considered. Mode (self-administration vs interviewer administration) and method for collection (eg, electronic medical record and paper) and tools for analysis and reporting (eg, ePRO) will vary based on the measure and can significantly impact the cost and support available at a particular institution.

At present, there is limited consensus for use of particular measures for patients with vascular diseases. However, there are some resources that can help to guide selection for subsets of vascular patients. For example, the SVS reporting guidelines for TOS recommend the use of the QuickDash and CBSQ scores (see Table III) in the assessment of patient response to treatment for neurogenic TOS.⁵⁰ However, a review of additional vascular-related guidelines and policy statements from large professional societies patients with PAD,^{1,95} venous disease,⁹⁶ and cardiovascular disease⁹⁷ did not yield any recommendations for specific endorsed PROMs. Additional resources for general guidelines to selection and best practices for PROM implementation include Health Measures⁹⁸ and the National Quality Forum.⁹⁹

VASCULAR SURGEON PERCEPTIONS OF PROMS: SURVEY DATA

A survey was designed by the members of the Patient Reported Outcomes subcommittee of the SVS Performance Measures Committee to address the barriers and facilitators to using PROMs in clinical practice (Supplementary Table, online only). The survey was distributed to 106 SVS members serving on committees

within the Policy and Advocacy Council. Of the 78 respondents completing the survey (response rate of 73.6%), 80.8% had heard of PROMs. All respondents (100%) who had heard of PROMs felt PROMs could be useful in assessing vascular surgery patients, particularly for patients with venous disease, PAD, and TOS (Fig). Only 23.1% of respondents indicated that their practice or institution used PROMs, although 80.0% indicated that their institution supported the use of PROMs. Of those respondents that actively used PROMs ($n = 10$ [12.8%]), the most common reason for collecting PROM data was for research and/or quality improvement initiatives (70.0%), followed by fulfilling an institutional requirement (50.0%), and quality reporting (40.0%). Nearly all respondents (90.0%) indicated they would consider using PROMs if they had the ability to incorporate the results into clinical practice, and 70.0% of respondents indicated they would consider using PROMs if they were incorporated into the electronic medical record. Reasons for not collecting PROMs were varied, and included concerns about available PROMs not being specific to patient problems and an inability to obtain results or analyze the collected data.

BARRIERS TO THE IMPLEMENTATION OF PROMS IN VASCULAR SURGERY: FOCUS GROUP DATA

Among those SVS members who completed the survey, a subset volunteered to participate in focus groups. Two 1-hour-long focus groups were conducted to assess granular perceptions of PROMs and preparedness of vascular surgeons for widespread implementation of PROMs. Focus group topics targeted physician awareness and knowledge of PROMs, the potential advantages and disadvantages of using PROMs in a vascular surgery practice, and any barriers that would impede PROM collection and interpretation.

The focus groups were conducted over video conference with a facilitator using a semistructured interview guide and were recorded. The recordings were professionally transcribed and transcripts were independently analyzed by three researchers who also participated in the focus group (C.H., A.V., and K.W.) and an additional analyst (M.R.). Transcripts were analyzed independently by at least two researchers for each transcript, who used open coding, resolved discrepancies with triangulation, and applied thematic analysis.¹⁰⁰ The analysis identified four themes from the focus group data: (1) knowledge gaps, (2) the usefulness of PROMs in vascular surgery, (3) barriers to use of PROMs, and (4) concerns regarding unintended consequences of using PROMs in measuring quality of care.

Knowledge gaps. Three subthemes were identified in knowledge gaps: a lack of (1) awareness of existing PROMs, (2) knowledge of how PROMs are developed and validated,

and (3) clarity around how PROMs should be used by the clinician. Regarding knowledge of existing PROMs, most participants were aware of types of measurements (eg, quality of life), but few were able to name specific measures and most were unaware that there were numerous validated PROMs relevant to vascular surgery patients. In addition, participants frequently conflated patient experience and satisfaction measures with HRQOL. Participants also described PROMs as a less rigorous form of data and felt that data reported by patients reflected opinion rather than outcome.

Focus group participants lacked an understanding of the rigorous development process that a validated PROM must undergo. In particular, there was a sentiment that PROM development and validation occurs in the absence of clinician participation. The participants believed that, if clinicians are not consulted or fail to participate in development or validation of PROMs, then it will be more challenging to ensure PROMs are applied and interpreted appropriately. However, participants did think that if recommendations for use of specific PROMs or guidelines on implementation and interpretation were released from known and respected specialty societies, they would be more likely to adopt and accept PROMs in their practice.

Finally, even among participants who had some experience with collection of PROMs, very few knew how to use PRO results to guide the care of individual patients in the way that traditional outcomes are used. The groups pointed out that the data depend not only on which PROM is used, but also when and how the information is collected. Although some participants had experience with PROMs in a research setting, there was little experience or knowledge of how PROMs might be reported to clinicians and how the reports could impact patient care. However, having acknowledged this limitation, surgeons agreed that the prevalence of PROMs in clinical practice is evolving and will likely take time before best practices can be established.

Usefulness of PROMs in vascular surgery. Two subthemes were identified in the usefulness of PROMs in vascular surgery: (1) the importance of incorporating the patient voice to define value, and (2) whether existing PROMs are capable of accounting for some of the confounding effect of patient morbidity on the outcome of care for vascular surgery patients. Participants agreed that the historical approach to patient care in medicine has failed to incorporate patient centeredness. Although the groups acknowledged that it may take time to determine what PROMs are most appropriate, the consensus was that failure to study the patient's perspective on their health outcomes will impede our ability to provide truly valuable care.

However, although participants felt strongly that PROMs could help to overcome physician bias for or

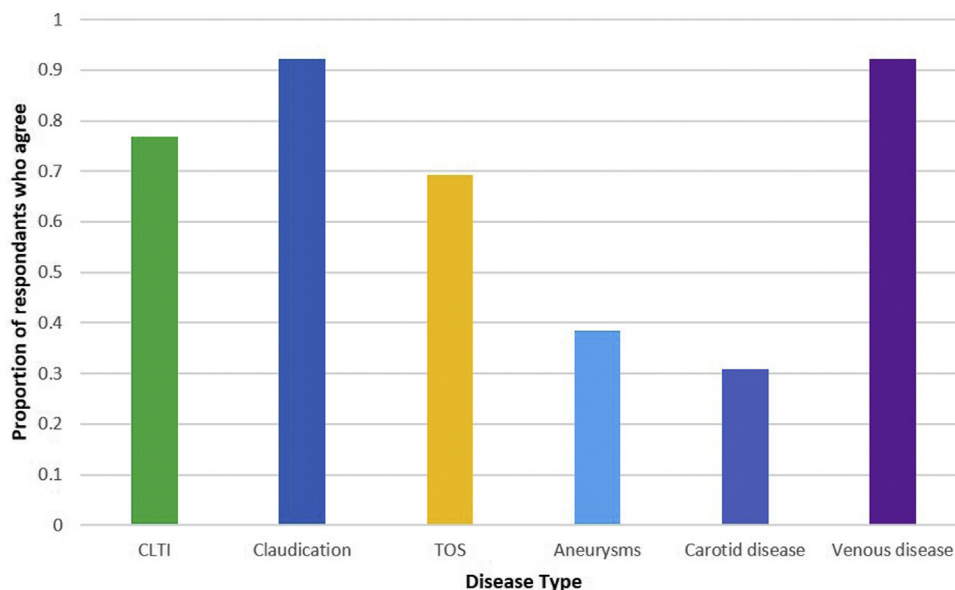


Fig. Summary of survey response answers to question about what patient groups patient-reported outcome measures (PROMs) may be helpful. *CLTI*, Chronic limb-threatening ischemia; *TOS*, thoracic outlet syndrome.

against how interventions or treatments impact a patient's health, the groups were also concerned about whether PROMs would be applicable universally, given the complexity and variability of vascular surgery patients. For example, the group expressed concern that PROMs may be less applicable in patients who have limited treatment options such as those with end-stage PAD with no potential for revascularization. In addition, participants felt strongly that risk adjustment must be applied to PROs given the prevalence of significant comorbidities in vascular surgery patients and variation in outcomes by region and institution.

Barriers to the use of PROMs. The focus groups identified two significant barriers to widespread use of PROMs: (1) logistical challenges of collecting and using PRO data, and (2) mistrust of outside oversight (eg, payors, employers) of outcome metrics. In the theme of logistical challenges, specific process barriers were identified that can be categorized under workflow and infrastructure. An example of infrastructure barriers is a lack of resources required to use an electronic device to capture responses. The group agreed that requiring patients to fill out paper forms that require manual entry into a database would likely require additional personnel or strain existing clinical staff. Even in centers where there was a potential for use of tablets or other electronic capture methods, surgeons acknowledged that the vascular surgery patient population is largely composed of elderly individuals who may have limited knowledge of or access to technology, therefore, potentially limiting the response rate in a typical practice. Furthermore, there may be a limited ability to capture these data within the electronic medical record itself,

decreasing the physician's ability to use the data for individual patients.

The groups expressed recurring concerns about how PROs would be interpreted not just by physicians but also by payors and policy makers. There was general concern about how PRO results would be used to measure the quality of care provided by physicians. Participants acknowledged that although most postoperative outcomes in vascular surgery are a direct consequence of the procedure, many short- and long-term outcomes are also directly impacted by comorbidities and the nature of the disease, and are independent of sound decision-making and/or a well-executed operation. There was hope, but also skepticism, regarding whether payors and policymakers would acknowledge the need for further study before determining how best to hold providers accountable to PRO results.

Unintended consequences. There were two sub-themes were identified in the unintended consequences that centered around the ethics of patient and procedure selection: (1) risk avoidance and (2) the appropriateness of procedures. The concept of risk avoidance, specifically physician avoidance of caring for high-risk patients, is not unique to PROs, but is a concern that physicians have expressed in response to public reporting of outcomes.¹⁰¹ The surgeons in the focus groups indicated that use of PROMs to measure quality of care may be even more likely to influence this practice than traditional outcomes.

Participants also suggested that PROMs may not correlate with the appropriateness of a procedure. For example, there are procedures in vascular surgery such as interventions for claudication or varicose veins that

may be associated with positive short-term impacts on a patient's health, but can be associated with high rates of recurrence or complications that negatively impact a patient's health in the long term. If PROs are considered in isolation without considering the appropriateness of the procedure, a positive result reported by a patient may inadvertently drive increases in certain procedures without consideration for appropriateness.

OVERCOMING THE BARRIERS

Based on our assessment of available vascular surgery-related PROMs, and feedback from the vascular surgery community, a number of actions are required to facilitate the widespread implementation of vascular surgery-related PROMs.

Development of vascular surgery-specific PROMs. Future vascular surgery-related PROMs should assess issues surrounding areas where there are no existing PROMs, including carotid disease, aortic dissection, chronic limb-threatening ischemia, and mesenteric disease. Currently, these issues are not addressed in existing vascular surgery PROMs and their assessment is critical to a comprehensive understanding of the effect that the spectrum of commonly performed vascular surgery operations and interventions have on a patient's HRQOL and satisfaction.

Recommendations for vascular surgery PROM best practices. Recommendations for best practices in areas including PROM selection, administration, recording of results, and the use of the results at both the individual and population levels should be developed. Recommendations should consider varying practice settings and available resources.

PROM education for the vascular surgery community. Education for the vascular surgery community is required about how PROMs are developed, available vascular surgery-related PROMs, the distinction between HRQOL and satisfaction, and how PROMs can be integrated into clinical practice to optimize patient outcomes and experience. Potential platforms for education include webinars, live events at professional meetings, web-based tutorials and printed materials such as newsletter articles and reviews in journals. The educational opportunities must be widely accessible and accommodate various preferences for learning.

Partnering with stakeholders. The most important stakeholder in addressing the issues surrounding vascular surgery PROMs is the patient. Future development and implementation efforts must include the patient voice and partner with patients to ensure success. Professional societies with shared interests in disease processes and treatments should work together in developing PROMs, best practices, and educational programming.

To incorporate PROs into reimbursement models, collaboration with payers, including the CMS, is required to optimize the method of implementation for both the clinician and the patient. Including PROs into reimbursement models should occur in a stepwise fashion with initial introduction as a process measure, to allow clinicians to acclimate to new practice elements.

CONCLUSIONS

PROs are gaining increased attention in all fields of medicine. A number of validated disease or procedure specific PROMs exist that are relevant to vascular surgery, including those for PAD, AAA, TOS, venous disease, wounds, and lymphedema. Based on survey and focus group data, there is strong support for the use of PROs in vascular surgery practice as a means to provide truly valuable care for our patients. However, several barriers exist to widespread implementation of PROs in vascular surgery. PRO collection is resource intensive and the widespread lack of education about the development, use, and potential harms related to PROM collection and reporting will significantly impede successful adoption. Further research is required to develop PROMs for all common vascular diseases and to ensure best practices around collection and interpretation. Societal leadership will play a pivotal role in defining how PROs may be best used in vascular surgery and collaboration with physicians, patients and payors will be vital to optimize patient care and improve patient-centered outcomes without encouraging risk avoidance or inappropriate care.

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Additional material for this article may be found online at www.jvascsurg.org.

Supplementary Table (online only). Survey questions circulated to Society for Vascular Surgery (SVS) members about their awareness, use, and implementation of patient-reported outcome measures (PROMs) in clinical practice

1. Have you heard of patient reported outcome measures (PROMs)?
 - Yes (go to #2)
 - No (survey stops)
2. Does your practice/institution use PROMs?
 - Yes
 - No
 - Don't know
3. How does your institution approach the use of PROMs?
 - Requires PROMs by all specialties (go to #4)
 - Requires PROMs by some specialties (go to #4)
 - Actively supports PROMs (go to #4)
 - Passively supports PROMs (go to #5)
 - Discourages the use of PROMs (go to #5)
 - Neither supports or discourages the use of PROMs (go to #5)
4. Are there specific ways your institution supports the use or implementation of PROMs (eg, PRO committee, EMR integration)?
 - Yes, please specify (free response)
 - No
5. Do you feel PROMs can be useful in assessing vascular surgery patients?
 - Yes (go to #5)
 - No (survey stops)
 - Don't know (go to #6)
6. Are there specific types of assessment or patient groups where you feel PROMs are most helpful? Select all that apply.
 - Chronic limb-threatening ischemia
 - Claudication
 - Thoracic outlet syndrome (TOS)
 - Aneurysm patients
 - Carotid disease
 - Venous disease
 - Other (fill in the blank)
7. Do you or your members in your practice use PROMs in the care of your patients?
 - Yes (go to #8)
 - No (go to #13)
8. What PROMs do you use and for which patients? Select all that apply.
 - General, please specify (free response)
 - Disease specific, please specify (free response)
 - Condition specific, please specify (free response)
 - Other (free response)
9. Follow-up for Q8—Please specify what type of PROMs you use.
 - Free response
10. Do the PROMs you collect impact your practice and if so, how? Select all that apply.
 - Quality reporting
 - Fulfills institutional requirement
 - Research/quality improvement interest
 - Other (free response)
11. Have you identified any barriers to collecting or utilizing PROMs? Select all that apply.
 - Poor patient participation
 - Difficulty getting reports/analyzing response
 - Other (free response)
12. What would most significantly facilitate use of PROMs for you/your practice? Select all that apply.
 - Incorporation into the EMR
 - Financial incentive
 - Ability to incorporate results to guide clinical practice
 - Other (free response)
13. Why do you not use PROMs in the care of your patients?
 - Too burdensome to collect
 - Not specific to patient problems
 - Difficulty entering answers into the EMR
 - They don't impact care provided
 - Other (please specify)
14. To your knowledge, does anyone else in your institution currently collect PROMs?
 - Yes
 - No
 - Don't Know
15. Anything else you would like to add (optional)?
16. Would you be willing to participate in a focus group or an individual interview to discuss using PROMs in your clinical practice in greater detail?
 - Yes (enter contact information)
 - No (survey stops)