SUPPLEMENTAL MATERIAL

METHODS

PROMs can be organized in different ways. Health status is often represented as a multidimensional construct that typically includes an assessment of patient-reported broad domains of functioning (physical, social, and emotional/mental) as defined by the World Health Organization's definition of health, and their subjective related concept quality of life (the degree to which a person's desired level of functioning differs from their actual state of functioning) as it relates to their health state.[1,2] A patient with symptomatic PAD may experience discomfort while walking in their calves ("symptoms"), this may limit their ability to walk more than a block ("physical functioning") but it may also affect their relationships and their ability to maintain their social life and mental well-being ("social and mental functioning"). A person who was recently very active may feel that these symptoms are very much limiting in their ability to lead their life as desired, whereas a very sedentary person, may not feel as much affected (their "quality of life").

While PROMs are multi-dimensional, there are examples of measures that are more specific and focus on a single subdomain of patients' physical functioning. Examples of those measures used in populations with symptomatic PAD populations are the Walking Impairment Questionnaire (WIQ) (disease-specific measure)[3] with a focus on difficulty walking distances, walking at various speeds, and on stair climbing. Examples of multi-dimensional disease-specific PROMs for patients with symptomatic PAD, include but are not limited to, the Peripheral Artery Questionnaire (PAQ),[4] the PAD Quality of Life Questionnaire (PADQOL),[5] and the Vascular Quality of Life Questionnaire (VascuQOL).[6]

PROMs can further be divided into *disease-specific* versus *generic measures*. Disease-specific PROMs are measures specifically designed to capture the symptoms, functioning, and quality of life as it relates to a specific disease state, such as PAD, whereas generic PROMs are used to capture an individual's overall health and is not specific to a particular disease. Whereas disease-specific PROMs are more sensitive to an individual's experience as it relates to the particular condition they are dealing with, generic PROMs capture patients' overall health-related functioning and quality of life which allows for

comparisons across different disease populations. Examples of generic PROMs include the SF-36 and the EQ-5D.[7,8]

PROM Validation Measures

Basic psychometric properties for PROMs necessary to establish construct validity include determining *("Does it measure what we think it measures?")*, the construct validity and sometimes, the clinical validity.[9] With this criterion, correlations are demonstrated between related constructs or domains from other, similar PROMs or clinical measurements. Higher correlations[10] between these related measures provide evidence for greater construct validity. To establish the reliability of a PROM, evidence in support of internal consistency (*"How reliably does this domain/PROM measure the construct that it intends to measure?")* is needed, which is a criterion for the interrelatedness of the items within a domain or domains of the PROM, and measured through the Cronbach's alpha (with a commonly accepted threshold of alpha > 0.80).[9,11] To further meet the criterion of reliability, one could also look for evidence that establishes the test-retest reliability (*"The degree to which two measurements in a short period of time are generating consistent results"*). Furthermore, PROMs need to establish their sensitivity to change (*"Can it detect meaningful changes in someone's health state?),* so that they can detect treatment effects, disease progression, and improvement.

RESULTS

Supplemental Table 4 lists the included disease-specific and generic PROMs and demonstrates the phase of validation work achieved by each PROM. The disease-specific PROMs included the PAQ (14 studies),[4,15,51-62] VascuQol (17)[6,19-27,30,63-68] WIQ (42),[3,14,16,29,32-45,69-92] Walking Estimated Limitation Calculated by History (WELCH) (9),[45,81,93-99] PADQoL (3),[5,28,100] Intermittent Claudication Questionnaire (ICQ) (5) (6),[26,28,46-48,76] VascuQoL-6 (4),[24,63,67,68,101] VascuQol-25 (1),[102] Claudication Symptom Instrument (CSI) (1),[103] Claudication Scale (4),[49,50,64,104] Edinburgh Claudication Questionnaire (6),[105-110] Patient Benefit Index for peripheral artery disease (PBI-PAD) (1),[111] PAVK-86 (1),[112] San Diego Claudication Questionnaire (1),[113] and the Australian Vascular Quality of Life Index (AUSVIQUOL) (1).[114] The generic PROMs used in symptomatic PAD were the SF-36 (33),[7,8,39,77-79,82,83,86,115-138] EQ-5D (16),[7,8,19,37,62,84,85,125,130,137,139-144] EACH-Q (4),[73,74,81,145] SF-12 (2),[17,144] SF-6D (1),[146] World Health Organization Quality of Life Assessment Instrument-100 (3),[129,147,148] McMaster Health Index Questionnaire (MHIQ) (2),[149,150] RAND-36 (9),[125,129-132,143,148,151,152] and the Nottingham Health Profile (NHP) (3).[125,135,153] Several reviews have examined multiple disease-specific and generic measures.[154-160]

Figure Legends

Figure S1. Flow diagram of articles included based on search strategy

Table S1. Summary of PROM-PAD Working Group meetings and stakeholder presence

Meeting Date & Location	Stakeholder Type	Number of Stakeholders Represented	Topics Discussed
January 14, 2019 **Washington DC**	Clinician Researchers, Regulatory, Reimbursement, Industry, Patient	37	• Landscape review including perspective presentations from each stakeholder group • Goal setting and gap analysis including discussion of "gold standard" objectives referencing the success of other fields • Discussion of patient perspective and priorities both generally and specific to certain outcome measures • Identification of potential research projects to advance patient reported outcomes measures in symptomatic PAD
May 3, 2019 **San Francisco, CA**	Clinician Researchers, Regulatory, Reimbursement, Industry	19	• Industry review of large clinical research studies leveraging patient reported outcomes measures that could be leveraged for future research • Additional insights from FDA on priorities and strategic approach to advancing and validating outcome measures • Preliminary prioritization of research projects and initiatives (pilot projects) to advance patient reported outcomes measures in symptomatic PAD • Consensus on manuscript approach and objectives, alignment of symptomatic PAD manuscript frameworks

Table S2. MESH terms used for search

Search Set	Search strategy	Results
#1 *Population: PAD or intermittent claudication*	"peripheral arterial disease"[MeSH Terms] OR "peripheral arterial disease"[tiab] OR "peripheral artery disease"[tiab] OR "intermittent claudication"[MeSH Terms] OR "intermittent claudication"[tiab] OR ("ischemia"[mesh] AND "Lower Extremity"[mesh]) OR "lower limb ischemia"[tiab] OR "lower limb ischaemia"[tiab] OR "critical limb ischemia"[tiab] OR "critical limb ischaemia"[tiab]	37,608
#2 *Patient-Reported Outcome Measures terms*	"Patient Reported Outcome Measures"[Mesh] OR (("patient reported"[tiab] OR "patient-reported"[tiab] OR "patient report"[tiab]) AND (measure*[tiab] OR outcome*[tiab])) OR PROM[tiab] OR PROMs[tiab] OR PROMIS[tiab] OR "PRO measure"[tiab] OR "PRO measures"[tiab] OR "portrait registry"[tiab]	36,853
#3 *Self-Report Terms*	"Self Report"[Mesh] OR "self report"[tiab] OR "self-report"[tiab] OR "self-reports"[tiab] OR "self reports"[tiab] OR "self-reported"[tiab] OR "self reported"[tiab] OR "self assessment"[tiab]	187,084
#4 *Names of specific tests / measures*	"PAQ"[tiab] OR "PADQOL"[tiab] OR "VascuQOL"[tiab] OR "ICQ"[tiab] OR "CLAU-S"[tiab] OR "WIQ"[tiab] OR "SF-36"[tiab] OR "SF-12"[tiab] OR "PROMIS"[tiab] OR "EQ-5D"[tiab] OR "VAS"[tiab] OR "walk test"[MeSH Terms] OR "walk test"[tiab] OR "6 minute walk test"[tiab] OR "RAND-36"[tiab] OR "RAND-12"[tiab] OR "treadmill"[tiab] OR "peripheral arterial questionnaire"[tiab] OR "peripheral artery questionnaire"[tiab] OR "quality of life questionnaire"[tiab] OR "vascular quality of life questionnaire"[tiab] OR "Intermittent Claudication Questionnaire"[tiab] OR "Claudication Scale"[tiab] OR "Walking Impairment Questionnaire"[tiab] OR "Short Form 36 Health Survey"[tiab] OR "short form-36"[tiab] OR "short-form 36"[tiab] OR "short form-12"[tiab] OR "Visual Analogue Scale"[tiab] OR "quality of life"[tiab] OR "portrait registry"[tiab] OR "Edinburgh Claudication Questionnaire"[tiab] OR "AUSVIQUOL"[tiab] OR "Baltimore activity scale"[tiab]	402,209
#5 *Combining w/ OR*	#2 OR #3 OR #4	588,439
#6 *Combining w/ AND*	#1 AND #5	2764
#7 *Excluding case reports, letters, editorials*	#6 NOT (Editorial[pt] OR Letter[pt] OR Case Reports[pt] OR Comment[pt])	2766
#8 *Excluding animal only studies*	#7 NOT (animals[mh] NOT humans[mh])	2634
#9 *Limit to English*	#8 AND English[lang]	2415
#10 *Limit date*	#9 AND ("1995/01/01"[Date - MeSH] : "2021/03/31"[Date - MeSH])	2198

Table S3. Comprehensive Review of Validation Studies by Psychometric Property and PROM

	Content Validity			Reliability		Sensitivity		Administration Logistics		
	Conceptual Framework/ Domains	**Content Validity**	**Construct Validity**	**Internal Consistency**	**Test-Retest Reliability**	**Sensitivity to Change**	**MCID**	**Time to Administer**	**Culturally Sensitive/ Translations Available?**	**Mode of Administration**
PAQ[4]	physical limitations, symptoms, social function, treatment satisfaction, quality of life, and summary score	literature and provider and patient input, but no details provided	ABI,*[2,3,7,9] Rutherford classification(modest correlation),[3] WIQ,* SF-36,* 7-day community steps,* EQ-5D*	.80-.94[4]	ICC 0.70 to 0.90 (2 weeks)	Guyatt Responsiveness Statistic = 4.1	Distribution-based interpretation in revascularization cohort, score of 8 points or greater corresponding to medium ES (50% of Standard Deviation)[12]	20-item, duration not described	Yes, Czech, Dutch (Netherlands),[6] English (UK, US),[4] French (Canada, France), German (Germany), Hebrew (Israel), Italian (Italy), Portuguese,[13] Korean,[8] Spanish[14] (US) and others (not published)[4,15,16]	self-report or interview-based
			factor analysis partially replication scales[15]			Various mean change scores reported for revascularization cohorts pre- and post that are statistically	Patient-anchor method in (global assessment of change) define a meaningful change as 10 points for both improvemen			

	Content Validity			Reliability		Sensitivity		Administration Logistics		
						different[9,12,17]	t and deterioration[18]			
VascuQoL[6]	activity, symptoms, pain, emotional, and social and index score (summary score)	Face validity of theVascuQol was examined in interviews with patients and a survey among health professionals	intermittent claudication distance,* maximum walking distance,* treadmill walking distance[19]*	Item-total score Cronbach α values exceeded .90.The item-domain score α values were all between .70 and .80[20,21]	intraclass (reliability) coefficient for test-retest scores was 0.91 (1 week); ICC for different domains ranged between 0.77-0.87[22]	Mean improvement in VascuQol summary score was 0.83. The correlation between the anchor-based rating of change questions and the VascuQol was 0.47. Standard response mean 1.02[21]	two anchor based methods for MCID calculation were applied. Two anchors were used: six global rating of change questions aimed at the VascuQol sumscore and subscales and the health transition item of the SF-36, both recorded at 12 months of follow up[25]	25 items, 9.6 minutes to complete	Yes, English (UK), Dutch (Netherlands), Swedish, Polish, Portugese (Brazilian), Norwegian and others (not published)[21,23,24]	self-report or interview-based

	Content Validity			Reliability		Sensitivity		Administration Logistics		
		Input from experts (providers and patients), literature review	In patients with IC, discriminate between walking distance (<=200m vs. >200m) AUC .65 (cross-sectional)[26]				Patients undergoing angioplasty with supervised exercise therapy for alleviation of IC			
		Candidate items were tested by patients for relevance (clinical impact factor)	In patients with IC, ability to detect change in Rutherford classification[26]				MCID for the VascuQol sumscore ranged between 1.19 and 1.66 for improvement and 0.08 and 0.41 for deterioration[25]			
		field testing with 10 patients	subscales validated against SF36 subscales and general health assessment[26]				0.87 for improvementsand 0.23 for deterioration (39)			
			6MWD[27]*							
			Fontaine classification*							

	Content Validity			Reliability		Sensitivity		Administration Logistics		
PADQOL[5]	Social relationships and interactions, self-concept and feelings, symptoms and limitations in physical functioning, fear and uncertainty, positive adaptation	Qualitative interviews with 38 patients with symptomatic PAD; interview participants then given developed questionnaire to get feedback	Relationship of the PADQOL subscale scores with the SF-36, WIQ, and POMS; Factor 1 and several SF-36 subscales (r=0.31 to 0.51); Factor 3 with SF-36 subscales (r=0.47-0.62) and WIQ subscales (r=0.50-0.57); Factor 5 poor correlation with SF-36, WIQ, and POMS subscales[5] Significant association between PADQOL social relationships and interactions and symptoms and limitations	Factor 1 : Cronbach α 0.92; Factor 2: Cronbach α 0.89; Factor 3: Cronbach α 0.88; Factor 4: Cronbach α 0.80; Factor 5: Cronbach α 0.73[5]				38 items, 9 minutes to complete		

	Content Validity			Reliability		Sensitivity		Administration Logistics		
			in physical functioning and the 6MWT p<0.001[28]							
WIQ[3]	Walking speed, distance, stair climbing ability, and limitations in walking ability	Development did not involve patients	WIQ score of 47and ability to complete 5-minute walk test on treadmill with 87% accuracy (AUC 0.906, p<0.001)[38] WIQ distance significantly correlated with ABI and maximal claudication distance[39] --- Significant correlation between change in WIQ and ACD[40]; WIQ distance score and 6MWT[3] ---	Cronbach's alpha for distance, speed, and stair-climbing subscales ranged from 0.82 to 0.94 in intermittent claudication[29]	ICC 0.72-0.89 for domains and for sumscore[29]	Improvement in WIQ scores after bypass surgery (6 weeks); after supervised walking (12 weeks)-Mays JVS	0.11 for improvement and -0.03 for deterioration [30,31]	22 questions; modified WIQ 16 questions	Yes, Spanish [32]; Chinese[33,34]; Korean[16]; Dutch[35]; Portuguese[36]	Self-administered and telephone administered[29,37]

	Content Validity			Reliability		Sensitivity		Administration Logistics		
			Moderate correlation with maximum walking distance[41,42] --- ABI and WIQ distance and speed subscale; ICD and ACD with WIQ pain and distance[43] --- 20 point declines in WIQ score associated with higher all-cause mortality[29] --- Significant association between steps walked daily and WIQ distance scores[44,45] --- Significant association between fast gait speed and WIQ stairs score							

	Content Validity			Reliability		Sensitivity		Administration Logistics		
ICQ[46]	Single index	Development involved interviews with patients with claudication; two vascular surgeons and two vascular nurses[46]	The ICQ correlated better with the EuroQol (r = 0.58) and 7 out of 8 subscales of the Short Form-36 (r = 0.33-0.68) compared with the WIQ. Significant association with ACD[46] Significant association between the ICQ and 6MWT P<0.001[28]	Cronbach's alpha 0.94 [46]	ICC 0.95[46]	Significant SRM values for patients who underwent angioplasty [46]		16 items; 3.7 minutes[46]	Turkish,[47] German[48]	Self-administered
CLAU-S[49,50]	Five domains: everyday life, pain, social living, illness specific fears, and psychological well-being		CLAUS sub-domains and ICD* and MWD[25]*					47 questions		

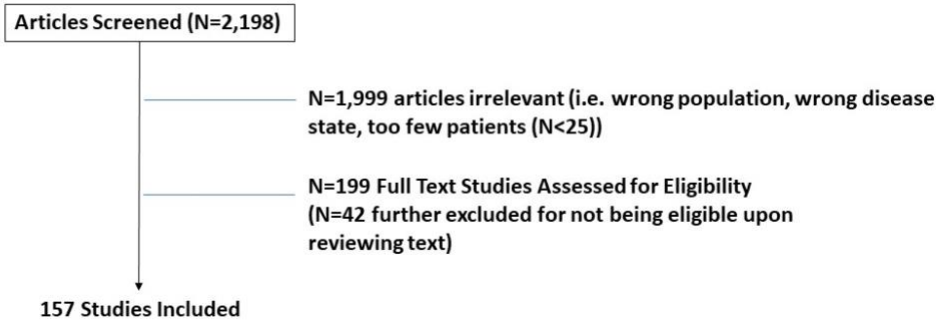
Table S4. Phases of validation achieved by each PROM

Instrument	Phase I	Phase II	Phase III
Disease Specific			
PAQ[4,15,51-62]	✓	✓	✓
VascuQOL[6,19-27,30,63-68]	✓	✓	✓
WIQ[3,14,16,29,32-45,69-92]	✓	✓	✓
WELCH[45,81,93-99]	✓	✓	
PADQOL[5,28,100]	✓	✓	
ICQ[26,28,46-48,76]	✓	✓	
VascuQoL-6[24,63,67,68,101]	✓	✓	
VascuQoL-25[102]	✓		
CSI[103]	✓		
CLAU-S[49,50,64,104]	✓		
Edinburgh Claudication Questionnaire[105-110]	✓		
PBI-PAD[111]	✓		

PAVK-86[112]	✓		
San Diego Claudication Questionnaire[113]	✓		
AUSVIQUOL[114]	✓	✓	
Generic			
SF-36[7,8,39,77-79,82,83,86,115-138]	✓	✓	✓
EQ-5D[7,8,19,37,62,84,85,125,130,137,139-144]	✓	✓	✓
EACH-Q[73,74,81,145]	✓	✓	
SF-12[17,144]	✓		
SF-6[146]	✓		
World Health Organization Quality of Life Assessement-100[129,147,148]	✓		
McMaster Health Index[149,150]	✓		
RAND-36[125,129-132,143,148,151,152]	✓		
NHP[125,135,153]	✓		

AUSVIQUOL indicates Australian Vascular Quality of Life Index; CLAU-S, Claudication Scale; CSI, Claudication Symptom Instrument; EACH-Q, Estimating Ambulation Capacity by History-Questionnaire; EQ-5D, European Quality of Life 5-Dimension; ICQ, Intermittent Claudication Questionnaire; NHP, Nottingham Health Profile; PADQOL, Peripheral Artery Disease Quality of Life; PAQ, Peripheral Artery Questionnaire; PAVK-86, Peripheral Artery Occlusive Disease 86; PBI-PAD, Patient Benefit Index for Peripheral Artery Disease; RAND-36, RAND 36-Item Health Survey; SF-6, 12, and 36, short form; VascuQOL, Vascular Quality of Life; WELCH, Walking Estimated-Limitation Calculated by History; WIQ, Walking Impairment Questionnaire

Figure S1.


Articles Screened (N=2,198)
N=1,999 articles irrelevant (i.e. wrong population, wrong disease state, too few patients (N<25))
N=199 Full Text Studies Assessed for Eligibility
(N=42 further excluded for not being eligible upon reviewing text)
157 Studies Included

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