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REVIEW ARTICLE

Richard P. Cambria, MD, Section Editor

Assessment of functional status and quality of life in claudication

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Background: **Treadmill walking is commonly used to evaluate walking impairment and efficacy of treatment for intermittent claudication (IC) in clinical and research settings. Although this is an important measure, it does not provide information about how patients perceive the effects of their treatments on more global measures of health-related quality of life (HRQOL).**
Methods: **PubMed/Medline was searched to find publications about the most commonly used questionnaires to assess functional status and/or general and disease-specific HRQOL in patients with peripheral artery disease (PAD) who experience IC. Inclusion criteria for questionnaires were based on existence of a body of literature in symptomatic PAD.**
Results: **Six general questionnaires and seven disease-specific questionnaires are included, with details about the number of domains covered and how each tool is scored. The Medical Outcomes Study Short Form 36-item questionnaire and Walking Impairment Questionnaire are currently the most used general and disease-specific questionnaires at baseline and after treatment for IC, respectively.**
Conclusions: **The use of tools that assess functional status and HRQOL has importance in both the clinical and research areas to assess treatment efficacy from the patient's perspective. Therefore, assessing HRQOL in addition to treadmill-measured walking ability provides insight as to the effects of treatments on patient outcomes and may help guide therapy.**
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Peripheral artery disease (PAD) results from atherosclerotic plaque in the major arteries of the lower extremities, causing decreased blood flow in the legs during exertion. Symptomatic PAD patients experience intermittent claudication (IC), which is characterized by cramping, fatigue and/or aching in the calves, thighs, or buttocks, typically brought on by walking and relieved by rest and which also causes impairments in quality of life.[1] Because of claudication pain, individuals with PAD often avoid physical activity, especially ambulation, thus leading to additional declines in functional status and health-related quality of life (HRQOL), defined as the patient's perceived physical, emotional, and social well-being and function.[2-4] PAD patients with IC may be limited in performing certain activities of daily living and may also feel that they are a burden to themselves as well as their family.[5]

It is important to assess how an individual perceives his or her own health because this information may be useful for determining appropriate treatment strategy and subsequently providing positive outcomes.[6] This review describes the impairments of functional status and HRQOL experienced by symptomatic PAD patients, as assessed by both general and PAD-specific questionnaires. The effects of PAD treatment (eg, supervised and unsupervised exercise, endovascular therapy, open-surgery procedures, medications) on functional status and HRQOL for patients with IC and the potential usage and relevance of these instruments in clinical and research settings is also discussed.

EPIDEMIOLOGY OF SYMPTOMATIC PAD

It has been estimated that 8 to 12 million adults have PAD in the U.S. and that approximately one-third experience IC.[7,8] According to the Trans-Atlantic InterSocietal Consensus II international guidelines, the prevalence of symptomatic PAD is approximately 2% to 7% in patients aged 50 to 70 years.[1] In addition to the high prevalence of IC, all persons with PAD have a significantly increased risk of cardiovascular morbidity and mortality.[9,10]

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Table I. Original development and validation studies for general questionnaires used in assessing functional status and/or health-related quality of life in symptomatic peripheral arterial disease patients

Questionnaires	*First author (year)*	*Domains/subscales*	*Items*	*Scoring range*[a]
SF-36	Ware[6] (1992) McHorney[113] (1993)	8	36	0-100
SF-12	Ware[28] (1996)	8	12	0-100
EuroQOL	EuroQOL group[31] (1990) Brooks[32] (1996)[b]	5	5	0-1
NHP	Hunt[43] (1980) Hunt[42] (1980)	7	45	100-0
WHOQOL-100	WHOQOL group[114] (1994) WHOQOL group[115] (1994)	6[c]	100	4-20[d]
MHIQ	Chambers[116] (1976) Sackett[117] (1977) Chambers[118] (1984)	3	59	0-1

EuroQOL, European Quality of Life questionnaire; *MHIQ*, McMaster Health Index Questionnaire; *NHP*, Nottingham Health Profile; *SF-12*, Short Form 12-item questionnaire; *SF-36*, Short Form 36-item questionnaire; *WHOQOL-100*, World Health Organization Quality of Life Assessment Instrument 100.
[a]Indicates worst to best.
[b]Description for five dimension version.
[c]Composed of 24 "facets" within the six quality of life domains.
[d]Scoring for each "facet" or domain.

OBJECTIVE MEASURES OF FUNCTIONAL STATUS IN CLAUDICATION

Treadmill testing is an established means to objectively determine walking ability in PAD patients and is highly predictive of long-term morbidity and mortality outcomes.[11,12] Typically, time and/or distance to onset of claudication and maximal time and/or distance walked until test termination due to leg pain are considered gold standard end points by which to assess walking ability for patients with IC. Other validated, objective physical measurements of functional status include the 6-minute walk test and the Short Physical Performance Battery.[13,14] These functional performance measures are more strongly associated with physical activity levels during daily life than treadmill walking and both are valid and reliable in objectively assessing physical function for patients with IC.[15-17] However, none of these tests address a patient's perception of his or her walking ability or HRQOL. In addition, other important elements of health status, such as mental health, emotional well-being, and social functioning, can be assessed only by questionnaires.

FUNCTIONAL STATUS/HRQOL QUESTIONNAIRES FOR SYMPTOMATIC PAD

Functional status can be defined ". . . as the level of activities performed by an individual to realize needs of daily living in many aspects of life, including physical, psychological, social, spiritual, intellectual, and roles."[18] HRQOL can be defined as an individual's multifaceted perception of his or her overall health and well-being, including the effect of illness, treatment, and other aspects of his or her daily life.[19,20] Questionnaire utilization has been a part of research studies seeking to evaluate functional status and HRQOL in cross-sectional evaluation or at baseline and after treatment for claudication. However, assessment of functional status and HRQOL in clinical settings using valid and reliable questionnaires is important in that appropriate questionnaires can assist health care providers in determining the level of impairment and selecting appropriate care for patients with IC. Questionnaires are often compared with objective measures such as treadmill walking to establish validity. There is also practical value for using questionnaires from a clinical standpoint, in that treadmill tests are more expensive than questionnaires.

Typically, two types of questionnaires are used in patients with IC. Functional status questionnaires focus primarily on the ability to complete physical activities and self-reported walking ability.[21] Domains such as life satisfaction, morale, and happiness are assessed by broader quality of life questionnaires that address overall well-being and function stemming from emotional and social aspects of life.[22] These types of questionnaires can be further divided into two main categories: general and disease-specific. General assessment tools are applicable to a wide range of patient populations, in contrast to disease-specific questionnaires. Tables I and II summarize the originating and/or validation studies for general and disease-specific questionnaires for PAD used in assessing functional status and HRQOL in symptomatic PAD patients.

General questionnaires. An important aspect of general health questionnaires is that comparative analyses can be performed in patient populations across disease states, thus providing the ability to describe the relative severity and effect of the disease in question. A number of general health questionnaires have been used to assess functional status and HRQOL for PAD patients with IC. Table III describes functional status and/or HRQOL after exercise training for patients with IC. Table IV summarizes the HRQOL outcomes after vascular procedures for the other tools described in this review. Table V describes the effect of pharmacologic therapies on quality of life assessed by questionnaires for patients with IC.

Table II. Original development and validation studies for disease-specific questionnaires used in assessing functional status and/or health-related quality of life in symptomatic peripheral arterial disease patients

Questionnaires	*First author (year)*	*Domains/subscales*	*Items*	*Scoring range*[a]
WIQ	Regensteiner[66] (1990)	4	22	0-100
CLAU-S	Finger[87] (1995)	5	47	0-100
PAVK-86	Heidrich[119] (1995)	7	86	4-1
VascuQOL	Morgan[96] (2001)	5	25	1-7
PAQ	Morgan[82] (2001)	7	20	0-100
SIP_{IC}	Gilson[103] (1975) Bergner[104] (1976) Arfvidsson[105] (1993)[b]	6[b]	12[b]	12-0[b]
ICQ	Chong[107] (2002)	1	16	0-100

CLAU-S, Claudication Scale; *ICQ,* Intermittent Claudication Questionnaire; *PAQ,* Peripheral Artery Questionnaire; *PAVK-86,* Peripheral Artery Occlusive Disease 86-item questionnaire; *SIP_{IC},* Sickness Impact Profile – Intermittent Claudication; *VascuQOL,* Vascular Quality of Life questionnaire; *WIQ,* Walking Impairment Questionnaire.
[a]Indicates worst to best.
[b]Describes the SIP_{IC} version of the questionnaire.

Table III. Functional status and/or health-related quality of life after exercise training for patients with intermittent claudication

First author (year)	*Sample size*[a]	*Interval*[a]	*Questionnaires*	*Type of training*	*Outcome*
Regensteiner[76] (1996)[b]	21	24 weeks	WIQ	Supervised exercise; strength training; nonexercise	Supervised group improved WIQ scores
Patterson[120] (1997)	38	24 weeks	SF-36	Supervised exercise; home-based exercise	Improvement in physical function, pain and physical component scores for both groups
Regensteiner[79] (1997)[b]	20	12 weeks	WIQ	Supervised exercise; unsupervised exercise	Supervised group improved WIQ walking distance and speed scores
Wullink[77] (2001)	24	24 weeks	WIQ	Unsupervised exercise[c]	Pain, distance, speed, and stair climbing domains improved but not significantly
Nicolai[78] (2009)	91	12 weeks	SF-36 EuroQOL WIQ	Supervised exercise	All WIQ domains improved; largest effect for SF-36 was pain and physical functioning; EuroQOL index improved
Nicolai[75] (2010)	252	1 year	SF-36 WIQ	Supervised exercise; supervised exercise;[d] unsupervised exercise	Physical summary score of SF-36 improved, no improvement in mental summary score; total WIQ scores improved

EuroQOL, European Quality of Life questionnaire; *SF-36,* Short Form 36-item questionnaire; *WIQ,* Walking Impairment Questionnaire.
[a]Indicates final sample size for claudicant patients and final outcome assessment time point.
[b]Also used SF-20, which was not discussed in this review.
[c]Used additional coaching in the home-based setting but did not directly supervise exercise.
[d]Provided an accelerometer to patients for additional feedback.

Short Form 36-Item questionnaire. The Medical Outcomes Study (MOS) Short Form (SF) questionnaires were constructed in part to provide practical tools for routine monitoring of patient outcomes in medical practice as well as for research.[23] The SF-36 provides a brief yet comprehensive assessment of HRQOL.[6] It measures eight domains: physical, role and social functioning, mental health, patient health perceptions, vitality, bodily pain, and change in health. The SF-36, for which each individual domain is transformed to a score of 0 to 100, with 100 being the best possible score (results can also be separated into physical and mental component summary scores), has been extensively validated for assessing HRQOL in symptomatic PAD patients. It is one of the most commonly used general health questionnaires for this purpose in addition to its broad use across many disease states.[24] PAD patients with IC report lower scores in physical functioning, physical limitations, and bodily pain compared with healthy controls and the general population.[25,26]

The MOS questionnaires have been used extensively to assess the results of bypass surgery, endovascular procedures, supervised exercise rehabilitation, and pharmaco-

Table IV. Functional status and/or health-related quality of life in symptomatic peripheral arterial disease patients after endovascular therapy and/or bypass surgery

First author (year)	*Sample size*[a]	*Interval*[a]	*Questionnaires*	*Vascular procedure*	*Outcomes*
Regensteiner[80] (1993)	14	12 weeks	WIQ	Bypass surgery;	All domains improved
Cook[33] (1996)	29	6 weeks	EuroQOL	Endovascular therapy	Both EuroQOL total and VAS scores improved
Cook[34] (1997)	24	1 year	EuroQOL	Endovascular therapy	EuroQOL total and VAS scores improved, except VAS perceived health state score
Chetter (1998)[35]	117	1 year	SF-36 EuroQOL	Endovascular therapy	Improved most domains, depending on site/severity of disease; no effect on psychological domains
Bosch[36] (1999)[b]	101	2 years	SF-36 EuroQOL	Endovascular therapy	Greatest effect in SF-36 physical functioning, physical role limitations and bodily pain; EuroQOL improved
Bosch[37] (2000)[b]	72	1 year	SF-36 EuroQOL	Endovascular therapy	Improvement in all SF-36 domains; increase in EuroQOL mobility, usual activities, pain/discomfort domains
Klevsgard[54] (2000)	67	24 weeks	NHP	Endovascular therapy; bypass surgery	Improved all domains except sex life
Klevsgard[52] (2001)	84	1 year	NHP	Endovascular therapy; bypass surgery	Improvements in Part I scores except social isolation for successful endovascular therapy; improved Part II scores of pain, emotional reactions
Klevsgard[53] (2002)	40	4 weeks	SF-36 NHP	Endovascular therapy; bypass surgery	[c]No improvement for SF-36 mental health or social functioning; no improvement for NHP social isolation, which was a zero value pre- and post
Wann-Hansson[55] (2004)	38	1 year	SF-36 NHP	Endovascular therapy; bypass surgery	Significant improvements in SF-36 bodily pain and physical functioning; no improvements in NHP scores
Spertus[82] (2004)	35	6 weeks	SF-36 WIQ PAQ	Endovascular therapy	Improvements in SF-36 physical, social domains and all WIQ and PAQ domains
Wann-Hansson[49] (2005)	51	4 years	NHP	Endovascular therapy; bypass surgery	Total NHP score improved compared to baseline
Murphy[81] (2005)	35	1 year	SF-36 WIQ	Endovascular therapy	SF-36 physical functioning, role physical, bodily pain, & vitality improved; all WIQ domains improved
Safley[30] (2007)	258	1 year	SF-12 EuroQOL PAQ	Endovascular therapy	Improvements in SF-12 and EuroQOL physical scores; all PAQ scores improved except treatment satisfaction
Egberg[38] (2010)	41	1 year	EuroQOL CLAU-S	Endovascular therapy	EuroQOL total index score and all 5 dimensions of CLAU-S improved

CLAU-S, Claudication Scale; *EuroQOL,* European Quality of Life questionnaire; *NHP,* Nottingham Health Profile; *PAQ,* Peripheral Artery Questionnaire; *SF-12,* Short Form 12-item questionnaire; *SF-36,* Short Form 36-item questionnaire; *VAS,* visual analogue scale; *WIQ,* Walking Impairment Questionnaire.
[a]Indicates final sample size for claudicants and final outcome assessment time point.
[b]Also used health utilities index, time tradeoff, standard gamble and rating scale instruments.
[c]After successful revascularization.

logic treatment. Recently, Mazari et al[27] examined the HRQOL of symptomatic PAD patients using the SF-36 before and 12 weeks after endovascular therapy, supervised exercise, and a combination of the two groups. Endovascular therapy and exercise training each independently resulted in improvements in the domains of physical functioning and physical role limitations. However, the combined interventions demonstrated the greatest impact on perceived quality of life, as six of the eight total domains of the SF-36 significantly improved. A number of studies have compared HRQOL across the different treatment options. Table VI summarizes the functional status and/or HRQOL questionnaires nested within individual studies after multiple interventions. Briefly, the most effective interventions for improving patient's quality of life included combinations of treatments.

SF 12-item questionnaire. The SF-12 extracts select items from all eight domains of the SF-36 and includes the same physical and mental component summary scores.[28] It was designed to be a simpler version of the SF-36, scored in the same way as the SF-36. Using the SF-12, Smolderen et al[29] assessed baseline HRQOL of symptomatic PAD patients compared with chronic heart failure patients. Results indicated that the physical domains were affected to a greater extent in PAD patients, whereas the mental domains were significantly worse in chronic heart failure pa-

Table V. Effects of pharmacologic therapy on functional status and/or health-related quality of life in symptomatic peripheral arterial disease patients

First author (year)	*Sample size*[a]	*Interval*[a]	*Questionnaires*	*Medication*	*Outcomes*
Creutzig[93] (1997)	93	12 weeks	SF-36 PAVK-86	PGE_1 (50 μg)	Greatest enhancements for SF-36 domains physical function, pain and physical role limitations; pain and functional status most improved PAVK-86 domains
Money[121] (1998)	212	16 weeks	SF-36 WIQ	Cilostazol (100 mg); placebo	Improvement in SF-36 physical domains and WIQ walking speed and measures of walking difficulty compared to placebo
Beebe[122] (1999)	413	24 weeks	SF-36 WIQ	Cilostazol (100 mg; 50 mg); placebo	Physical health domains of SF-36 improved for both cilostazol groups compared to placebo; WIQ walking speed and distance better in both cilostazol groups
Hiatt[123] (2001)	155	24 weeks	SF-36 WIQ	Propionyl-L-carnitine (6 mg); placebo	Propionyl-L-carnitine improved SF-36 domains of physical role functioning, bodily pain and health transition scores; also improved WIQ distance and speed scores
Strandness[86] (2002)	286	24 weeks	SF-36 WIQ	Cilostazol (100 mg; 50 mg); placebo	Time point analysis indicated improvements in all physical domains for cilostazol vs placebo groups
Hiatt[83] (2004)	300	24 weeks	SF-36 WIQ	[b]AT-1015 (10 mg; 20 mg; 40 mg); placebo	No differences among SF-36 and WIQ scores between groups
Hiatt[84] (2004)	328	1 year	WIQ	Avasimibe (50 mg; 250 mg; 750-mg); placebo	Greatest enhancement in WIQ distance score seen in group receiving 50-mg dosage
Creager[124] (2008)	214	24 weeks	SF-36 WIQ	Iloprost (50 μg; 100 μg; 150 μg) Pentoxifylline (400 mg); placebo	No differences between groups for SF-36; stair-climbing only WIQ domain to improve

PAVK-86, Peripheral Artery Occlusive Disease 86-item questionnaire; *PGE_1,* prostaglandin E_1; *SF-36,* Short Form 36-item questionnaire; *WIQ,* Walking Impairment Questionnaire.

[a]Indicates final sample size of claudicants and final outcome assessment time point.

[b]5-HT2A serotonin receptor antagonist.

tients. Safley et al[30] established that the physical component summary scores improved after endovascular therapy in a cohort of mostly PAD patients with claudication and a small number of patients with critical limb ischemia (CLI), similar to studies using other versions of the MOS Short Form. More research is needed to determine the effect of other treatment methods on SF-12 scores for symptomatic PAD patients. However, because it is a relatively short questionnaire compared with other general health questionnaires, it may be practical for use in clinical settings.

European Quality of Life Questionnaire. The European Quality of Life Questionnaire (EuroQOL) is a combined functional status and HRQOL instrument that assesses five domains, including mobility, self-care, usual activities, pain/discomfort, and anxiety/depression.[31,32] The questionnaire administrator scores the EuroQOL by applying a single summary index from 0 to 1, with 0 representing the worst health state and 1 representing perfect health. A second, separate part of the EuroQOL is the visual analogue scale (VAS), which asks patients to draw a line on a 0 to 100 "thermometer" scale, rating their health from worst imaginable health to best imaginable health (transformed to the summary index of 0 to 1 as well).

The EuroQOL has been used to examine the effects of endovascular therapy for PAD patients. Generally, endovascular therapy improved many of the domains included in the questionnaire.[30,33-38] Several studies have also compared treatments, including supervised exercise, endovascular therapy, and optimal medical therapy.[39-41] Spronk et al[41] found that endovascular therapy and supervised exercise training both resulted in improved EuroQOL scores 6 and 12 months after treatment. There were no differences between the treatment groups, suggesting that supervised exercise and endovascular therapy have similar value for improving HRQOL for up to 1 year. The EuroQOL is a brief, easy-to-use questionnaire that may have practical value for use in clinical settings.

Nottingham Health Profile. The Nottingham Health Profile (NHP) evaluates functional status and HRQOL and has been used for patients with IC, primarily in European studies.[22,42,43] The NHP contains two sections: Section I is

Table VI. Studies employing general and disease-specific questionnaires to assess functional status and/or health-related quality of life in symptomatic peripheral arterial disease patients within multiple interventions

First author (year)	*Sample size*[a]	*Interval*[a]	*Questionnaires*	*Interventions*	*Most effective intervention*
Currie[125] (1995)	186	12 weeks	SF-36	Endovascular therapy; bypass surgery; unsupervised exercise	Endovascular therapy and bypass surgery
Whyman[51] (1996)	62	24 weeks	NHP	Endovascular and medical therapy; medical therapy	Endovascular and medical therapy
Whyman[50] (1997)	62	2 years	NHP	Endovascular and medical therapy; medical therapy	No differences between groups
De Vries[39] (2005)	348	24 weeks	SF-36 EuroQOL VascuQOL	Endovascular therapy; bypass surgery; medical therapy	Did not distinguish HRQOL between groups
Kakkos[109] (2005)[b]	26	24 weeks	SF-36 WIQ ICQ	Supervised exercise; unsupervised exercise; IPC	IPC and supervised exercise
Imfeld[95] (2006)	55	24 weeks	SF-36 WIQ PAVK-86	Supervised exercise; supervised exercise and medication;[c] home-based exercise	Inconclusive
Mehta[40] (2006)	70	24 weeks	SF-36 EuroQOL VascuQOL SIP_{IC} CLAU-S	Endovascular therapy; medical therapy	Endovascular therapy
Nylaende[91] (2007)	48	2 years	SF-36 EuroQOL[d] CLAU-S	Endovascular and medical therapy; medical therapy	Endovascular and medical therapy
Spronk[41] (2008)	150	1 year	SF-36 EuroQOL	Endovascular therapy; supervised exercise	Supervised exercise
Mazari[27] (2010)	157	12 weeks	SF-36 VascuQOL	Endovascular therapy; supervised exercise;[e] combined group	Combined group

CLAU-S, Claudication Scale; *EuroQOL,* European Quality of Life questionnaire; *ICQ,* Intermittent Claudication Questionnaire; *IPC,* intermittent pneumatic compression; *NHP,* Nottingham Health Profile; *PAVK-86,* Peripheral Artery Occlusive Disease 86-item questionnaire; *SF-36,* Short Form 36-item questionnaire; *SIP_{IC},* Sickness Impact Profile – Intermittent Claudication; *VascuQOL,* Vascular Quality of Life questionnaire; *WIQ,* Walking Impairment Questionnaire.

[a]Indicates final sample size for claudicants and final outcome assessment time point.

[b]Six month active treatment time point described.

[c]Clopidgrel, 75-mg once daily.

[d]Used the visual analogue scale.

[e]Patients completed a circuit exercise program.

composed of 38 yes/no response items and six domains that include sleep, energy, emotional reactions, social isolation, physical mobility, and pain. Section II examines patient difficulties with daily activities by using seven general yes/no questions. These include the areas of employment, housework, family relationships, social life, sex life, hobbies, and holidays. Higher scores indicate greater health problems, on a scale of 0 to 100. Studies have examined HRQOL using the NHP for claudicant patients compared with controls or CLI patients.[44-46] Khaira et al[46] demonstrated that symptomatic PAD patients have greater impairments in the NHP domains of energy, pain, emotional reactions, sleep, and physical mobility compared with age and sex-matched controls. Klevsgard et al[44] determined that the areas of pain, sleep, and physical mobility are significantly better for PAD patients with IC compared with CLI patients, with no differences in energy, emotional reaction, or social isolation.

Other studies have yielded mixed results when examining the change in HRQOL after vascular intervention for IC.[47-55] Koivunen and Lukkarinen[47] determined that revascularization improved the domains of emotional reactions, energy, and social isolation. In addition, lower extremity bypass surgery also improved pain, physical mobility, and sleep 1 year after the intervention.[47] However, recently it was found that quality of life returned to presurgery levels in the domains of pain and physical mobility at 1 year of follow-up.[48] These findings suggest that although endovascular therapy improves HRQOL acutely, long-term outcomes may not be as durable. The NHP is comprehensive and has been examined extensively in research settings. This questionnaire may be practical for use in clinical settings because it takes only 5 to 10 minutes to complete.[53,55]

World Health Organization Quality of Life Assessment Instrument 100. The World Health Organization Quality of Life Assessment Instrument 100 (WHOQOL-100) was designed for cross-cultural applicability and thus was developed in several different languages.[56-60] The instrument is composed of six domains, including physical health, psychological state, level of independence, social relations, environment, and spirituality, religion, and per-

sonal beliefs, incorporating 24 quality of life "facets" and 100 total items. Responses are determined from 5-point Likert scales (eg, very dissatisfied = 1; very satisfied = 5). Using a reduced version of the WHOQOL-100 (17 facets), Breek et al[60] established that patients with IC had lower scores in the domains of physical health and level of independence as well as many facets compared with healthy controls. In one of the few studies to use the WHOQOL-100 to evaluate an intervention (ie, angioplasty, bypass surgery, endarterectomy, amputation) for patients with IC, there were improvements in physical health and level of independence.[61] Although the WHOQOL-100 is well established in other disease states, more studies are warranted to determine the effect of treatment on HRQOL for IC. The original questionnaire is probably too long to be practical for clinical use, but the reduced version may have value for use in the clinical setting.[57]

McMaster Health Index Questionnaire. McMaster Health Index Questionnaire (MHIQ) is composed of 59 health-related items covering physical, social, and emotional dimensions. The physical function domain consists of 24 items, including physical activities, mobility, and self-care activities. There are 25 social function items that assess general welfare, family, and friend's support and participation, and global social function. The 25 emotional function items include self-esteem, feelings about personal relationships, thoughts about the future, critical life events, and global emotional function. Because some of the items address both social and emotional functions within the same question, the consolidated number of items is 59. For each of the three dimensions, scores are based on index values of 0 to 1, with lower scores indicating worse function. Compared with other general questionnaires, few studies have used the MHIQ to assess HRQOL in patients with IC.[62,63] However, findings indicate impairments in general health and physical, social, and emotional function when compared with age-matched controls.[63] After 24 weeks of pharmacologic therapy, Brevetti et al[64] found that patients randomized to receive propionyl-L-carnitine improved physical and emotional function and the global scores compared with the group receiving a placebo. There may be use for this questionnaire in clinical settings.

PAD-SPECIFIC QUESTIONNAIRES

Disease-specific HRQOL questionnaires for PAD were developed to examine how IC affects the well-being and ability of patients to function. Although less generalizable than HRQOL questionnaires developed for use across disease states, these tools allow for a more in-depth assessment of specific health issues related to PAD. This is particularly important because of the debilitating effects of IC on HRQOL, particularly in the physical domains compared with the psychosocial domains.[65]

Walking Impairment Questionnaire. The Walking Impairment Questionnaire (WIQ) was one of the first disease-specific questionnaires for assessing functional status in PAD patients and remains widely used.[66] The WIQ was validated in several large studies and is available in many different languages.[67-72] In the initial validation as well as in subsequent studies, the questionnaire results were correlated to treadmill measures of performance (ie, peak walking distance, peak oxygen consumption, and onset of claudication pain) in PAD patients.[66] The WIQ assesses how limited patients are in walking defined distances and speeds and the degree of difficulty climbing flights of stairs. Symptoms that limit walking are also assessed. Scoring is on a 0% to 100% scale. The WIQ has been used to establish that limitations in walking speeds and distances as well as in stair climbing are present in patients with IC compared with controls.[4,73] The WIQ has also been shown to detect impairment in PAD patients who have mild symptoms or are asymptomatic.[74]

The WIQ has been used extensively to evaluate the efficacy of several types of therapy for IC, including exercise training,[66,75-79] peripheral bypass surgery,[66,80] endovascular therapy,[81,82] and many types of medications.[83-86] In the initial development and validation, Regensteiner et al[66] compared WIQ scores of claudication patients before and after 12 weeks of supervised treadmill walking and 6 weeks after bypass surgery. Both treatments significantly improved the distance and speed domains as well as treadmill walking, demonstrating the positive impact of both treatments. Matsuo and Shigematsu[85] examined changes in functional status assessed by the Japanese version of the WIQ for IC patients. Patients were stratified by ankle-brachial index values and treated for 8 weeks with prostaglandin E_1 in lipid microspheres. The WIQ subscales improved for all groups, demonstrating sensitivity to the treatment. Thus, the WIQ is a valid, reliable, and sensitive tool for assessing functional status of PAD patients for available treatment options. This questionnaire is brief and can be used in the clinical or research settings to provide information about walking impairment.

Claudication Scale. The Claudication Scale (CLAU-S) was originally developed in Germany and has been translated into a number of different languages, including French, English, Flemish, and Swiss.[38,87,88] The different versions of this scale are composed of Likert scale items, each with a number of domains. The six-domain version includes daily living, pain, complaints, social life, disease-specific fears, and mood. Scoring is on a 0 to 100 scale (ie, 0 = worst score, 100 = best score). Most of the studies using the CLAU-S in European settings have examined the effects of naftidrofuryl (a 5-hydroxytryptamine-2 receptor antagonist), a peripheral vasodilator, on IC and have demonstrated mixed results for specific domains, although walking improvement has been observed. Daily living, pain, disease-specific fears, and mood improved significantly compared with patients who received a placebo.[89] However, D'Hooge et al[90] found no changes in disease-specific fears and mood and an improvement in social life scores after naftidrofuryl treatment. Several vascular intervention studies have evaluated changes in HRQOL demonstrating both short- and long-term improvements in most of the domains of the CLAU-S.[38,91] To the best of our knowl-

edge, the CLAU-S has only been used in the research setting to date.

Peripheral Artery Occlusive Disease 86 questionnaire. The Peripheral Artery Occlusive Disease 86 (PAVK-86) consists of 86 items and seven HRQOL domains that include functional status, pain, general complaints, mood, anxiety, social life, and evaluation of treatment. Scoring is from 1 to 4, with 1 indicating no impairment and 4 indicating high impairment. Holler et al[92] examined PAVK-86 scores spanning PAD severity according to the Fontaine Classification system (stages II to IV). Patients experienced greater impairments in pain and functional status between Fontaine Classification Stage IIb (moderate to severe claudication) compared with IIa (mild claudication), indicating that the more advanced disease and subsequent shorter distance to onset of leg pain leads to a greater impairment of the PAVK-86 physical domains. The PAVK-86 has been used to evaluate changes in HRQOL after pharmacologic treatment, supervised and unsupervised exercise training, and combined pharmacologic and supervised exercise training.[93-95] Briefly, all domains except general complaints improved in patients with IC after 12 weeks of supervised treadmill walking.[94] The largest improvement was demonstrated in the pain and functional status domains, indicating that physical domains for IC patients are generally the most improved by exercise training. One drawback is that the questionnaire has proven difficult and lengthy for patients to complete.[92]

Vascular Quality of Life questionnaire. The Vascular Quality of Life (VascuQOL) questionnaire was originally developed for use in patients with Fontaine classification II-IV (ie, ranging from mild IC to ulceration/gangrene) and has been translated into multiple languages.[96] The questionnaire contains 25 items subdivided into the domains of pain, symptoms, activities, and social and emotional well-being. Scores are based on responses from a 7-point scale for each item (1 being the lowest score, 7 being highest). Several studies have used it to evaluate the effect of IC on quality of life.[39,97] de Vries et al[39] established that the instrument discriminated disease severity among PAD patients. The tool has also been demonstrated to be sensitive to change in HRQOL after various treatments for IC.[27,39,40,98] For instance, Roberts et al[98] found that an unsupervised, home-based exercise program improved all domains of the VascuQOL, except for the social domain. The original study indicated that the questionnaire was easy for patients to understand and took an average of 9.6 minutes to complete, indicating it may have value in clinical settings.[96]

Peripheral Artery Questionnaire. The Peripheral Artery Questionnaire (PAQ) is a disease-specific health status questionnaire for patients with PAD.[82,99,100] There are 20 items scored from worst (0) to best (100) relating to domains specific to PAD, including (1) identification of the most symptomatic leg, (2) degree to which PAD limits normal activities, (3) questions regarding recent improvement or deterioration in symptoms, (4) the frequency and intensity of claudication, (5) questions regarding patient satisfaction with current treatment, (6) standard quality of life and current symptoms and limitations compared with their desired level of functioning, and (7) social function.[82] In the initial validation study using revascularization, scores improved significantly in all PAQ domains. Several current studies have examined the validity of the PAQ, including several using a Dutch version of the scale.[30,101,102] The questionnaire is relatively brief and may be useful in the clinical setting.

Sickness Impact Profile–Intermittent Claudication. The Sickness Impact Profile–Intermittent Claudication (SIP_{IC}), developed from the generic HRQOL 136-item SIP, is a condensed version of the original, containing 12 items from six domains.[103-105] The domains that comprise the SIP_{IC} are sleep and rest, home management, ambulation, mobility, social interaction and alertness, and behavior. Scoring is completed by a positive response to a specific question (eg, 1 point for acknowledgment of walking shorter distances or stopping to rest often). Although many studies use the original SIP across various disease states, relatively few have used the SIP_{IC} version for symptomatic PAD patients after treatment.[40,106] Taft et al[106] examined differences in HRQOL assessed by the SIP_{IC} in stable IC after several different interventions. Patients who received endovascular therapy/bypass surgery significantly improved SIP_{IC} scores and also demonstrated larger improvements from baseline than the supervised exercise training and control groups. There may be utility in the clinical setting for this questionnaire because of its brevity.

Intermittent Claudication Questionnaire. The Intermittent Claudication Questionnaire (ICQ) consists of an index of 16 items that focuses on limitations imposed by claudication while performing various tasks, such as walking specific distances or performing errands.[107] This questionnaire is a relatively new tool for assessing HRQOL in PAD patients after treatment. Cheetham et al[108] demonstrated that a supervised exercise program improved ICQ scores by 43% from baseline scores, whereas an advice-only group had a nonsignificant improvement of 16% (also used SF-36). Additionally, Kakkos et al[109] examined quality of life at baseline and after supervised and unsupervised exercise and intermittent pneumatic compression for patients with stable IC. Supervised exercise and intermittent pneumatic compression both improved ICQ scores at 6 weeks and 6 months after baseline. The questionnaire has also been validated in Turkish.[110] Overall, testing for use in symptomatic PAD patients has been limited. However, the ICQ may be a practical tool for use in clinical settings because the average time for completing the questionnaire is 3.7 minutes.[107]

CLINICAL RELEVANCE OF HRQOL AND FUNCTIONAL STATUS ASSESSMENT

The questionnaires discussed in this review have been more commonly used in the research setting than the clinical setting. Finding reports about results of questionnaire use in the clinical setting is difficult because often clinicians may not publish results of a questionnaire used

only in this way. Although many study results are adopted into clinical practice, there are not direct examples in the literature of a claudication research trial substantially altering clinical management as a result of questionnaire use. However, the role for questionnaires in the clinical setting should be further explored because patient outcomes provide important information about treatment efficacy. For instance, understanding patient goals may help in making treatment decisions. The treatment options presented to the patient may not meet their expectations, which may affect adherence to the treatment and could adversely affect the patient's physical, mental, and emotional satisfaction with care.[111] Assessing HRQOL and functional status may assist in circumventing future problems with treatment choice and ultimately improve the health of PAD patients with claudication.

CONCLUSIONS

HRQOL is defined as a patient's perceived physical, emotional, and social well-being and function. It has been estimated that >2 million individuals with IC have a reduced quality of life, particularly relating to limitations in ambulation.[10,112] It is important for health care providers to evaluate the burden of the disease, which ultimately will guide selection of appropriate treatments for improving the HRQOL of PAD patients. Thus, questionnaires that are simple, accurate, and effective for determining perceived quality of life and functional status in patients with IC have utility in clinical as well as research settings. Future research should move toward a consensus on the best questionnaires available for symptomatic PAD patients and standardize the implementation and interpretation of these tools in clinical settings.

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