

PATIENT-REPORTED OUTCOME MEASURES IN PATIENTS WITH PERIPHERAL ARTERY DISEASE: A SYSTEMATIC REVIEW

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Introduction

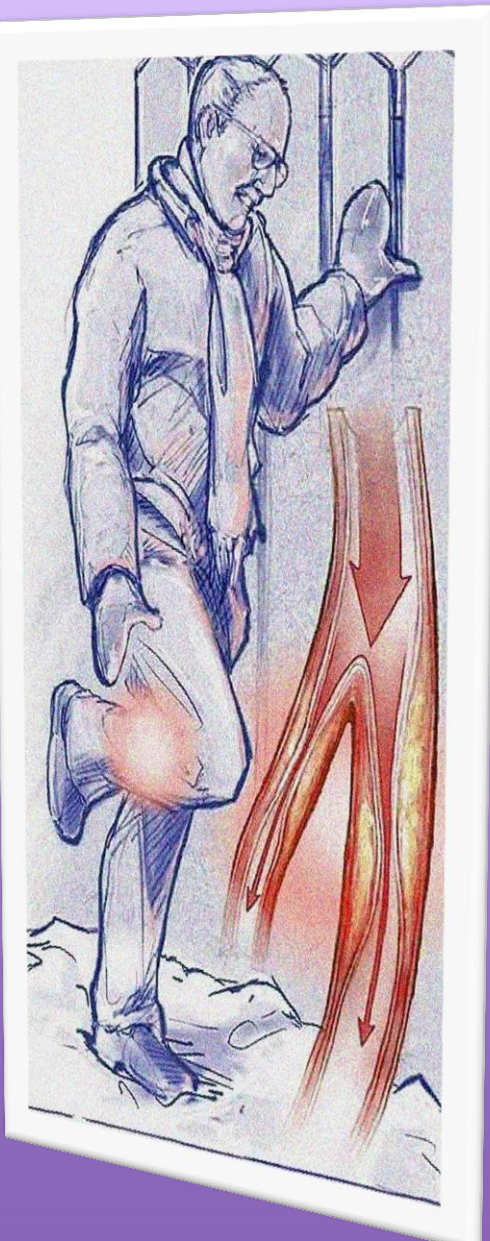
Peripheral artery disease (PAD) in the lower limbs is a clinical presentation of generalised atherosclerosis and is common in people aged 70 years.^{1, 2} Symptomatic PAD results in significant functional limitations and reduced health-related quality of life (HRQoL).^{3,4} To help capture the impact of treatments provided to affected patients by Vascular Services in the UK, it is important to use appropriate PROMs for assessing patients in the relevant setting.

The aim of this review was to identify validated PROMs and to select appropriate PROMs for the clinical assessment of patients with PAD in the UK.

Methods

The review was conducted in accordance to the Preferred Reporting Items for Systematic Reviews and Meta-analysis recommendations. Reported measurement properties (domains) of identified PROMs were summarised using psychometric and operational criteria based on the COSMIN criteria⁵ and the Oxford system.⁶ The combined rating scales were (0) for not reported, (-) for evidence not in favour, (+/-)for conflicting evidence, (+) for evidence in favour.

SYSTEMATIC REVIEW	
Literature searching	Two-staged search - to find all potentially relevant PROMs to add to those already known (Search 1) - to identify studies reporting the validation of PROMs retrieved (Search 2)
Data sources	Medline and Medline in Process, EMBASE, Cochrane Library, CINAHL, PsychINFO, Web of Science, PROQOLID, PROMs Bibliography (Oxford University)
Search Dates	Initial searches: - From database inception to August 2013 (Search 1); February 2014 (Search 2) Updated searches: - Medline and Medline in Process, January 2015
Study selection	Prospective studies assessing the measurement properties of eligible PROMs in a well-defined population of English-speaking patients with PAD
Data extraction	Items relating to - study characteristics; - patient characteristics; - psychometric evaluation of PROMs
Quality assessment	Based on COSMIN criteria
Data synthesis	Tabular and narrative summaries



Source: <http://www.southernvascularspecialist.com.au/Peripheral-Arterial-Disease.html>

CRITERIA FOR ASSESSING REPORTED DOMAINS	
Domain	Criteria
Test re-test	Intraclass correlation coefficient or weighted kappa score between ≥0.70 (for group comparisons) and ≥ 0.90
Internal consistency	Cronbach's alpha score between ≥0.70 and ≥0.92 for group comparisons
Content validity	Item total correlations ≥0.20 Clear description of development of instrument using patients, aim of measurement, item selection, target population, concepts to be measured
Construct validity	Correlation co-efficient of ≥0.60
Criterion validity	Good argument for accepting an instrument as a gold standard reported
Responsiveness	Correlation between PROM and the gold standard , ≥ 0.70 Statistically significant changes in score of an expected magnitude based on methods including either t-tests, effect size, standardised response means or Guyatts' responsiveness index
Floor-ceiling effects	Presence of floor or ceiling effect if >15% of respondents achieved the lowest or the highest score on the instrument, respectively
Acceptability	Applied to items and summary scores < 80%

Results

Of 6,682 screened records, 15 prospective studies were included. There was one international study, remaining studies were conducted in Australia (n = 1), UK (n = 7) and USA (n = 6). Studies were diverse in terms of study population. Additionally, there was no evidence relating to defined populations with advanced PAD or full psychometric evaluation of a single PROM.

PSYCHOMETRIC PROPERTIES OF GENERIC PROMS							
	1	2	3	4	5	6	7
<i>SF-36</i>							
Mehta (2006)	0	0	0	-/+	-/+	0	0
Smith (2007)	-	+	0	-/+	0	0	0
Spertus (2003)	-/+	0	0	+	0	0	0
Chong (2002)	0	0	0	-	+	0	0
Coyne (2003)	0	0	0	+	0	0	0
Izquierdo-Porrera (2005)	0	0	0	+	0	0	0
Gulati (2009)	0	+	0	0	0	0	0
Morgan (2001)	0	0	0	+	0	0	0
Chetter (1997)	0	+	0	-/+	-/+	0	0
Treat-Jacobson (2012)	0	0	0	-/+	0	0	0
Mazari (2010)	0	0	0	-/+	+	0	0
<i>SF-8</i>							
Gulati (2009)	0	+	0	+	-/+	0	0
<i>EQ-5D</i>							
Mehta (2006)	0	0	0	0	+	0	0
Chong (2002)	0	0	0	-/+	+	0	0
Coyne (2003)	0	0	0	-/+	0	0	0
Chetter (1997)	0	+	0	+	+	0	0
Mazari (2010)	0	0	0	+	-/+	0	0
<i>NHP</i>							
Chetter (1997)	0	+	0	+	+	0	0
<i>POMS</i>							
Treat-Jacobson (2012)	0	0	0	-/+	0	0	0

Key: (1), internal consistency; (2), test-re-test reliability; (3), content validity; (4), construct validity; (5), responsiveness; (6), flooring/ ceiling effect; (7), acceptability

Abbreviations:

Generic PROMs: EQ-5D, EuroQol; NHP, Nottingham Health Profile; POMS, Profile of Mood States; SF-36, Medical Outcomes Study 36-item Short Form

Condition-specific PROMs: AUSVIQUOL, Australian Vascular Quality of Life Index; CLAU-S, Claudication Scale; EACH-Q, Estimation of Ambulatory Capacity by History-Questionnaire; ICQ, Intermittent Claudication Questionnaire; PADQOL, Peripheral arterial disease (PAD) Quality of Life Questionnaire; PAQ, Peripheral Artery Questionnaire; SIPic, Sickness Impact Profile – Intermittent Claudication; VascuQoL, King's College Hospital's Vascular Quality of Life instrument; WIQ, Walking Impairment Questionnaire

PSYCHOMETRIC PROPERTIES OF CONDITION-SPECIFIC PROMS							
	1	2	3	4	5	6	7
<i>CLAU-S</i>							
Marquis (2001)	+	?	0	-/+	-/+	0	0
Mehta (2006)	0	0	0	-/+	-/+	0	0
<i>VASCUQOL</i>							
Mehta (2006)	0	0	0	-/+	-/+	0	0
Morgan (2001)	+	-/+	+	+	+	0	0
Mazari (2010)	0	0	0	+	+	0	0
<i>AUSVIQUOL</i>							
Smith (2007)	-/+	+	0	-/+	0	0	0
<i>PAQ</i>							
Spertus (2003)	+	+	0	+	+	0	0
<i>PADQOL</i>							
Treat-Jacobson (2012)	+	0	+	-/+	0	0	0
<i>ICQ</i>							
Chong (2002)	-	+	+	-/+	+	0	0
<i>SIPic</i>							
Mehta (2006)	0	0	0	-/+	-	0	0
<i>WIQ</i>							
Spertus (2003)	-/+	+	0	+	-/+	0	0
Tew (2013)	0	0	0	0	0	0	-
Treat-Jacobson (2012)	0	0	0	-/+	0	0	0
Chong (2002)	0	0	0	-/+	-	0	0
Coyne (2003)	-/+	-/+	0	+	0	0	0
McDermott (1998)	0	0	0	+	0	0	0
Izquierdo-Porrera (2005)	0	0	0	-/+	0	0	0
Regensteiner (1990)	0	-/+	0	+	+	0	0
<i>EACH-Q</i>							
Tew (2013)	0	0	0	0	0	0	-

Key: (1), internal consistency; (2), test-re-test reliability; (3), content validity; (4), construct validity; (5), responsiveness; (6), flooring/ ceiling effect; (7), acceptability

Conclusions

- Available evidence demonstrates extensive clinical heterogeneity and methodological quality in studies examining measurement properties of PROMs in patients with peripheral arterial disease.
- Although validation did not cover all relevant measurement properties, the VascuQoL and the Peripheral Arterial Questionnaire demonstrated relatively good psychometric properties, whereas the WIQ appeared to be a good measure of functional status.
- To ensure effective capture of the impact of the PAD, careful selection of appropriate PROMs in routine clinical use is essential.

References

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