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Title: Patient-Reported Outcome Measures in Carotid Artery Revascularisation: Systematic Review and Psychometric Analysis

Authors: Munira Essat[a*], Ahmed Aber[a], Patrick Phillips[a], Edith Poku[a], Helen Buckley Woods[a], Aoife Howard[a], Simon Palfreyman[b], Eva Kaltenthaler[a], Georgina Jones[c], Jonathan Michaels[a]

Munira Essat, University of Sheffield, m.essat@sheffield.ac.uk
Ahmed Aber, University of Sheffield, a.aber@sheffield.ac.uk
Patrick Phillips, University of Sheffield, p.phillips@sheffield.ac.uk
Edith Poku, University of Sheffield, e.poku@sheffield.ac.uk
Helen Buckley Woods, University of Sheffield, h.b.woods@sheffield.ac.uk
Aoife Howard, University of Sheffield, aoife.howard@sheffield.ac.uk
Simon Palfreyman, University of Alberta, simon.palfreyman@ualberta.ca
Eva Kaltenthaler, University of Sheffield, e.kaltenthaler@sheffield.ac.uk
Georgina Jones, Leeds Beckett University, g.l.jones@leedsbeckett.ac.uk
Jonathan Michaels, University of Sheffield, j.michaels@sheffield.ac.uk

[a]School of Health and Related Research, University of Sheffield, Sheffield, S1 4AD
[b]University of Alberta, 116 St & 85 Ave, Edmonton, AB T6G 2R3, Canada
[c]Instituation: School of Social Sciences, Leeds Beckett University, Leeds, LS1 3HE

*Corresponding author: Munira Essat, Regent Court, 30 Regent Street, School of Health and Related Research, University of Sheffield, Sheffield, S1 4DA.
E-mail: m.essat@sheffield.ac.uk.

26 Tel: +44 (0) 114 222 0860

27 Fax: +44 (0) 114 222 0749

Abstract

Objective:

Patient-reported outcome measures (PROMs) provide a way to measure the impact of a disease and its associated treatments on the quality of life from the patients' perspective. The aim of this review was to identify PROMs that have been developed and/or validated in patients with carotid artery stenosis (CAS) undergoing revascularisation and to assess their psychometric properties and examine suitability for research and clinical use.

Methods:

Eight electronic databases including MEDLINE and CINAHL were searched using a two-stage search approach to identify studies reporting the development and/or validation of relevant PROMs in patients with CAS undergoing revascularisation. Supplementary citation searching and hand-searching reference lists of included studies were also undertaken. The COnsensus-based Standards for the selection of health Measurement INstruments (COSMIN) and Oxford criteria were used to assess the methodological quality of the included studies and the psychometric properties of the PROMs were evaluated using established assessment criteria.

Results:

Five studies reporting on six PROMs were included: 36-Item Short Form Health Survey (SF-36), Euro-QoL-5-Dimension Scale (EQ-5D), Hospital Anxiety and Depression Scale (HADS), Dizziness Handicap Inventory (DHI), Quality of life for carotid artery disease scale and a disease-specific PROM for CAS. The rigour of the psychometric assessment of the PROMs was variable with most only attempting to assess a single psychometric criterion. No study reported evidence on construct validity and test-retest reliability. Evidence for acceptability for the use of SF-36, EQ-5D and the disease-specific PROM were rated good in most studies. Only one study reported a Cronbach alpha score >0.70 as evidence of internal

consistency. Overall, the psychometric evaluation of all included PROMs was rated as poor within the CAS population undergoing revascularisation.

Conclusions:

This review highlighted a lack of evidence in validated PROMs used for patients undergoing carotid artery revascularisation. As a result, the development and validation of a new PROM for this patient population is warranted in order to provide data which can supplement traditional clinical outcomes (stroke<30 days post-procedural, myocardial infarction and death) and capture changes in health status and quality of life to help inform treatment decisions.

Keywords: Carotid artery revascularisation; Patient-Reported Outcome Measures; PROMs; Quality of life; Vascular surgery; Psychometric.

1. Introduction

Thromboembolism from carotid artery stenosis (CAS) is a major cause of stroke, accounting for one in five cases of all strokes.[1] Patients with CAS can remain asymptomatic until the carotid arteries are severely narrowed or blocked and in some cases transient ischaemic attack or stroke is the first sign of the disease. Patients with severely narrowed or blocked arteries may undergo a surgical procedure to open the arteries and to prevent stroke and its complications from occurring, namely death or decrease in quality of life (QoL).

Patient reported outcome measures (PROMs) are questionnaires completed by the patient in relation to their health and daily functioning. This provides a way of measuring the impact of a disease and its associated treatments on the health and QoL from the patients' perspective.[2] PROMs can be categorised as generic, disease-specific or dimensional specific (measure the effect of an intervention on a specific concept e.g. anxiety). Generic PROMs can be used in a variety of conditions and allows comparison across different patient groups. In contrast, disease-specific PROMs are specific to treatments and symptoms associated with a particular disease or condition. Both generic and disease-specific PROMs can be preference-based PROMs and can be used to estimate preference weights for calculating quality-adjusted life-years, from which an economic value of interventions can be assessed.[3;4]

The United States Food and Drug Administration (FDA) recommends the use of both generic and disease-specific measures in clinical trials[5] and in the United Kingdom the National Institute for Health and Care Excellence (NICE) use PROMs data to facilitate health technology assessments.[6] Since 2009 the NHS has made it a requirement to collect PROM data from patients before and after surgery in four surgical conditions: hip replacement, knee replacement, varicose vein treatment and groin hernia repair. Currently, PROMs are not

routinely used in carotid artery revascularisation. The addition of validated PROMs to the hard clinical outcomes (i.e. stroke < 30 days post-procedural, myocardial infarction and death) in patients undergoing carotid artery revascularisation, can provide information about the quality of care and the impact of treatment on a patient's QoL including wound complications, cranial nerve damage, drug side effects and anxiety associated with the condition and treatments.[7] It is important to use PROMs that have followed best practice in terms of their development and evaluation to ensure the PROMs are 'appropriate and comprehensive relative to its intended measurement concept, population, and use'.[2]

The aim of this review was to identify studies reporting on the development and/or validation of PROMs for use in patients with CAS undergoing revascularisation, critically appraise the psychometric properties of the PROMs, and examine its suitability for clinical and research use. This review forms part of a larger study funded by the NIHR examining the re-configuration of vascular services in the UK and identify targets for future research.

2. Methods

This systematic review was reported in accordance with the general principles recommended in the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[8] A protocol was developed and registered on the PROSPERO international prospective register of systematic reviews (http://www.crd.york.ac.uk/PROSPERO/display_record.php?ID=CRD42015023877).

2.1 Data sources and searches

Systematic searches were undertaken in eight electronic databases and research registers including MEDLINE, MEDLINE in Process, EMBASE, the Cochrane Library, CINAHL,

PROQOLID, PsychINFO and Web of Science. A two-stage search approach was used. The first stage combined known generic and condition-specific terms for PROMs and CAS. The studies were retrieved and examined for additional PROM terms used in CAS. Stage 2 incorporated PROM terms identified in stage 1 with a preliminary search strategy and a methodological search filter for finding studies on measurement properties.[9] Databases were searched from inception up to February 2015 (for stage 1) and up to May 2015 (for stage 2). Both searches were updated in February 2017. No language or date restrictions were applied. Searches were supplemented by hand-searching the reference lists of relevant reviews and included studies, citation searching and contact with experts in the field. Details of the search strategies are provided in Supplementary Appendix 1.

2.2 Study selection

All identified titles were examined for inclusion and any citations that clearly did not meet the inclusion criteria were excluded (e.g. non-human, unrelated to CAS). All abstracts and full text articles were then examined by at least two reviewers. Any disagreements in the selection process were resolved by discussion, with involvement of a third reviewer when necessary. A summary of the inclusion and exclusion criteria is presented in Table I.

Table I: Study Selection Criteria

	Inclusion criteria	Exclusion criteria
Population	A defined population of participants with a confirmed diagnosis of CAS (using ultrasonography, computed tomography, magnetic resonance imaging, or	Patients not diagnosed with CAS

	conventional angiography) who need, have had, or are undergoing revascularisation.	
Intervention	Any surgical treatment indicated for CAS e.g. carotid endarterectomy, carotid artery stenting and angioplasty	Non-surgical interventions for CAS
Outcomes	PROMs (including generic, disease-specific, preference-based, functional and symptoms) used to assess quality of life in patients with CAS undergoing revascularisation	Outcome measures of patient satisfaction or experience in the relevant population PROMs from Proxy
Study design	Any	
Publication type	Published or unpublished full-text peer reviewed journal articles including structured abstracts with all relevant information	Reviews, Editorial and Opinion pieces
Language	English	Non-English

CAS, carotid artery stenosis; PROMs, Patient reported outcome measures;

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135 **2.3 Data abstraction**

136 Data relating to study design, patient characteristics, type of surgical treatment, type of

137 PROM used, methods and outcomes were extracted by one reviewer into a standardised data

extraction form, and independently checked for accuracy by a second. Any discrepancies were resolved by discussion, with involvement of a third reviewer, if required.

2.4 Psychometric evaluation

The methodological quality and the psychometric properties of the included PROMs were assessed by two independent reviewers. Any disagreements were resolved by discussion and when needed with the involvement of a third reviewer. Criteria used to appraise the PROMs (see Table II) were adapted from published recommendations.[10-16] These criteria have been successfully applied previously[17;18] and are consistent with the FDA guidance.[2] The instruments were examined for their reliability (the degree to which measures are reproducible and consistent over time in patients with a stable condition); validity (the degree to which the instrument measures what it is supposed to measure); responsiveness (the degree to which the instrument detects meaningful change over time if a change truly exists) and acceptability (the degree to which the instrument is acceptable to the patients). As no gold standard exists for QoL, criterion validity was not assessed.

Table II: Appraisal criteria for assessing the psychometric properties of patient-reported outcome measures

Domain	Sub-domain	Criteria
Reliability	Test re-test	The intra-class correlation/ weighted kappa score should be ≥0.70 for group comparisons and ≥ 0.90 if scores are going to be used for decisions about an individual based on their score.[10]
		The mean difference (paired t test or Wilcoxon signed-

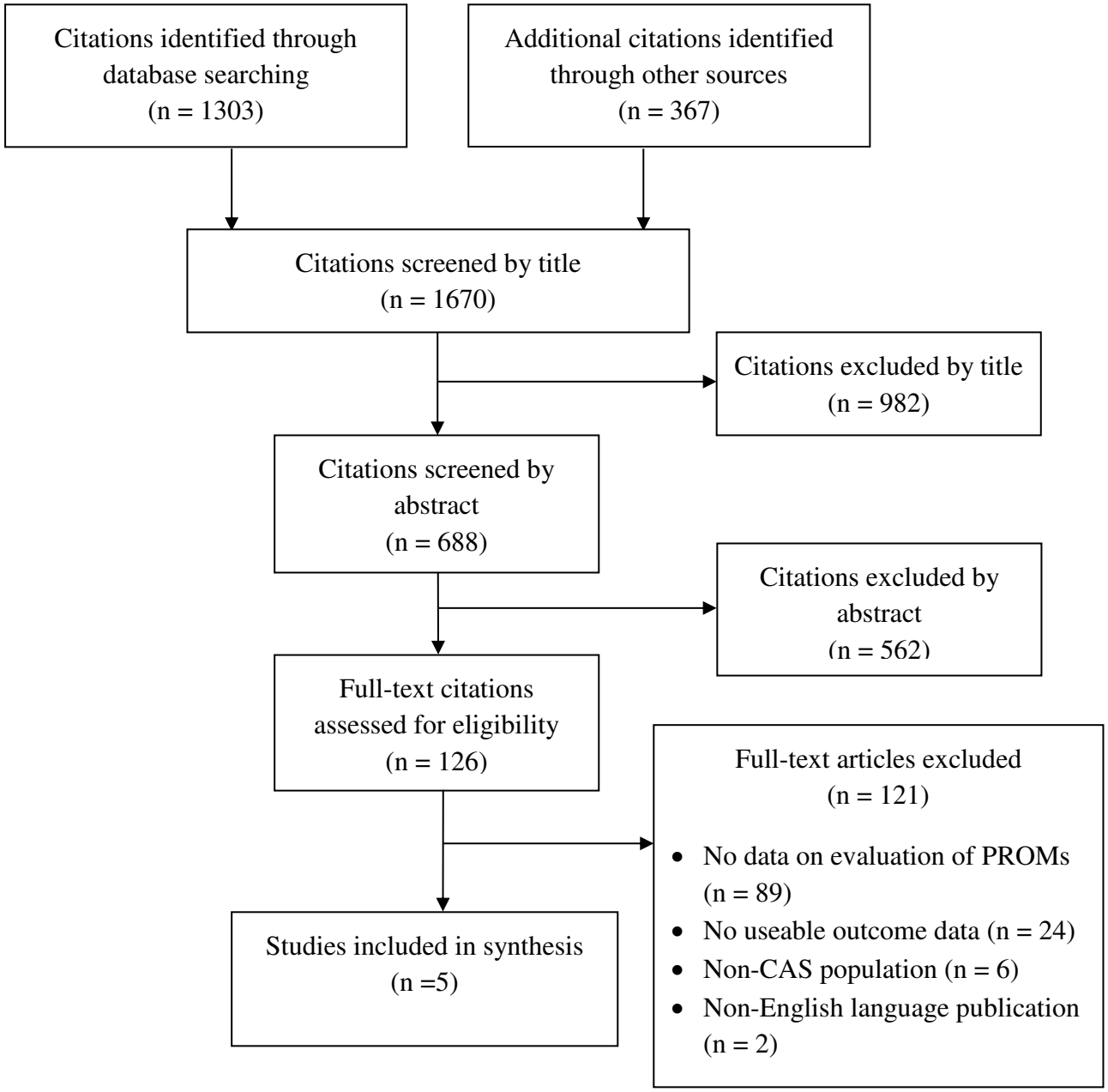
		rank test) between time point 1 (T_1) and time point 2 (T_2) and the 95% CI should also be reported.
	Internal consistency	A Cronbach's alpha score of ≥0.70 is considered good and it should not exceed ≥0.92 for group comparisons as this is taken to indicate that items in the scale could be redundant. Item total correlations should be ≥0.20.[13]
Validity	Content validity	This is assessed qualitatively during the development of an instrument. To achieve good content validity, there must be evidence that the instrument has been developed by consulting patients, experts as well as undertaking a literature review. Patients should be involved in the development stage and item generation. The opinion of patient representatives should be sought on the constructed scale.[10;12;13]
	Construct validity	A correlation co-efficient of ≥0.60 is taken as strong evidence of construct validity. Authors should make specific directional hypotheses and estimate the strength of correlation before testing.[10;13;14]
Responsiveness	Responsiveness	There are a number of methods to measure this including t-tests, effect size, standardised response means or responsiveness statistics Guyatts' responsiveness index.[16] There should be statistically significant changes in score of an expected

		magnitude.[15]
Acceptability	Floor-ceiling effects	A floor or celling effect is considered if 15% of respondents are achieving the lowest or the highest score on the instrument.[14]
	Acceptability	Acceptability was measured by the completeness of the data supplied. 80% or more of the data should be complete.[12]

3. Results

A total of 1,670 records were identified, of which 126 full-text articles were considered eligible for inclusion. Following detailed examination, five studies (reporting on the development and/or validation of six PROMs) were included in this review. All the included studies reported the validation or development of PROMs in patients with symptomatic and/or asymptomatic CAS undergoing surgical treatment. The majority of the excluded studies did not present data evaluating the measurement properties of PROMs and only reported the use of PROMs in patients with CAS undergoing revascularisation. A summary of the process for identifying and selecting the relevant literature is presented in Figure 1.

Figure 1: Study flow chart (adapted) of study selection



3.1 Study characteristics

Table III presents the study characteristics of the five included studies. All the included studies used PROMs to assess the health related quality of life (HRQoL) or functional status of patients undergoing revascularisation and reported aspects of the methodological details of the PROMs development and/or validation. The studies were prospective in design and were undertaken in the USA,[19] Germany,[20] USA/ Canada,[21] Taiwan[22] and Latvia.[23] The studies were published between 2010[19] and 2015,[23] and the majority of the studies were of a small to moderate size with the number of participants ranging from 61[22] to 2502.[21] Adults of either sex were recruited with the proportion of men ranging between 55%[23] to 84%[22] and the mean age range between 69 years[21] and 73 years.[22]

The patients' clinical diagnosis varied across studies: four studies[19-22] included patients with both symptomatic and asymptomatic carotid artery stenosis, whilst one study, Ivanova et al[23] only included asymptomatic patients. The types of surgical treatment reported for carotid revascularisation included carotid endarterectomy (CEA),[20;23] carotid artery stenting (CS)[22] and in two studies[19;21] both CS and CEA were used.

Table III: Study and patient characteristics of included studies reporting validation of PROMs in patients

Author, year	Country	Diagnosis (Sample size)	Age, years (mean ±SD)	Gender n/N (% males)	Reported PROM(s)	Timing of PROM(s) assessment	Treatment

Stolker 2010[19]	USA (SAPPHIRE Trial)	High risk patients symptomatic and asymptomatic **(N=310)**	72 (± 8)	211/310 (68.1)	EQ-5D SF-36 Disease-specific PROM	Baseline, 2 weeks, 1,6 and 12 months post-surgery	CEA versus CS in high risk patients
Attigah 2011[20]	Germany	Symptomatic and asymptomatic carotid stenosis **(N=102)**	Median age (range): 70 (42-86)	70/102 (68.6)	HADS EQ-5D	1 day before and 2 days post-surgery	Local anaesthetic in CEA
Cohen 2011[21]	USA &Canada (CREST Trial)	Symptomatic and asymptomatic carotid stenosis **(N=2,502)**	69 (NR)	1626/2502 (65)	SF-36 Disease-specific PROM	Baseline, 2 weeks, 1 month and 1 year post-surgery	CEA versus CS
Hsu 2014[22]	Taiwan	Symptomatic and asymptomatic carotid stenosis **(N=61)**	73.3 (± 10.5)	51/61 (83.6)	SF-36 DHI	1 week before, 1 and 6 months post-surgery	CS

Ivanova 2015[23]	Latvia	Asymptomatic carotid artery stenosis **(N=120)**	Median age (range): 69.3 (42-84)	66/120 (55)	Quality of life for carotid artery disease	1,3,6,9,12 months before entry and 4 months until total of 24 months	CEA

CS, carotid artery stenting; CEA, carotid endarterectomy; CREST, Carotid Revascularisation Endarterectomy Versus Stenting Trial; DHI, Dizziness Handicap Impact; SAPPHIRE, Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy; PROMs, patient reported outcome measure; SD, standard deviation; NR, not reported

3.2 PROMs data and psychometric evaluation

Five studies reported data relating to the psychometric evaluation of PROMs in patients undergoing carotid revascularisation. Of these, two were generic PROMs: 36-item Short Form Health Survey (SF-36)[19;21;22] and Euro-QoL 5 Dimension Scale (EQ-5D).[19;20] Two were dimension-specific PROMs: Hospital Anxiety & Depression scale (HADS)[20] - a mental health specific PROM and Dizziness Handicap Inventory (DHI)[22]. Two were condition-specific PROMs: Quality of life for carotid artery disease scale designed by Ivanova et al[23] and a disease-specific PROM for CAS[19] which was designed for use in the SAPPHIRE trial (Stenting and Angioplasty with Protection in Patients at High Risk for Endarterectomy)[19] and was further adapted and used in the CREST study (Carotid Revascularization Endarterectomy versus Stenting Trial).[21]

The timings of administering the PROMs were different between the five studies. The shortest post intervention follow-up was two days and the longest was 24 months. The rigour of the psychometric assessment of the PROMs was variable, with most only attempting to assess a single psychometric criterion. The evaluation was generally poor across all the included studies in this review. The results of the psychometric evaluation are presented in Table IV. In brief, the quality of each psychometric criterion was based on: 1) using the appropriate statistical test for a specific criterion and 2) the results of the test fulfilled the criteria mentioned in the methods section and Table II. Each criterion was evaluated independently and objectively by two independent reviewers.

Table IV: Summary of the psychometric properties of patient-reported outcome measures

PROM	Internal consistency	Test re-test Reliability	Content validity	Construct validity	Responsiv-eness	Floor/ ceiling	Acceptability
SF-36							
Cohen 2011[21]	0	0	0	0	+/-	0	+
Stolker 2010[19]	0	0	-	0	+/-	0	+
Hsu 2014[22]	?	0	0	0	0	0	0
EQ-5D							
Stolker 2010[19]	0	0	-	0	+/-	0	+

Attigah 2011[20]	0	0	0	0	?	0	0
Disease-Specific PROM							
Cohen 2011[21]	0	0	-	0	?	0	+
Stolker 2011[19]	0	0	-	0	?	0	+
Quality of Life for Carotid Artery Disease							
Ivanova 2015[23]	0	0	+/-	0	-	-	0
DHI							
Hsu 2014[22]	0	0	0	0	?	0	0
HADS							
Attigah 2011[20]	0	0	0	0	?	0	0

DHI, Dizziness Handicap Impact; EQ-5D, EuroQol 5 dimensions; HADS, hospital anxiety and depression scale; PROMs, patient reported outcome measures; SF-36, 36-item Short Form Medical Outcomes Study

Psychometric and operational criteria:

0	Not reported (no evaluation completed)
-	Evidence not in favour
-/+	Weak evidence
+	Evidence in favour
?	Methodology questionable

The SAPPHIRE trial[19] included high-risk patients with symptomatic carotid stenosis of >50% and patients with asymptomatic CAS with >80% stenosis. Patients were randomised to either the CS arm (159 patients) or the CEA arm (151 patients). HRQoL was assessed at baseline, two weeks and one, six and 12 months using SF-36, EQ-5D and a disease-specific PROM with six questions asking about difficulty with walking, eating/swallowing, driving, headache, neck pain and leg pain. The study did not report any qualitative evidence to support the content validity of the disease-specific PROM. Only four- subscales of the SF-36 were used (physical function, role limitations, pain, vitality), the authors justified this decision that only these four dimensions were sensitive to differences between CS versus CEA and provided no further evidence. However, data on three of these subscales were not sensitive at all and did not show any statistically significant change from baseline, only the physical scale of SF-36 showed some responsiveness at two weeks. The disease-specific PROM in this study did not undergo further psychometric analysis to assess its responsiveness. The strongest feature of PROMs used in this study was acceptability with data completeness being above 80%.

The CREST trial[21] included data from 2,502 patients with symptomatic and asymptomatic CAS. 1,262 patients were assigned to CS and 1,240 to the CEA arm of the trial. HRQoL was assessed at baseline, two weeks, one month and one year post intervention using SF-36 and an adapted version of the disease-specific PROM from the SAPPHIRE trial.[19] The disease-specific PROM included eight questions (including difficulty in walking, difficulty in swallowing/eating, driving, neck pain, headaches, leg pain, level of overall pain and the number of times pain medications were needed). No qualitative evidence for content validity, internal consistency and reliability of either instrument was provided. However, both instruments showed good acceptability with data completion rates of 85 to 90%. The SF-36

scores improved across five out of eight dimensions of health (P value < 0.01) at two weeks for patients undergoing CS versus CEA.

Attigh et al[20] assessed HRQoL in 102 patients undergoing CEA under local anaesthetic. The SF-36 and HADS were used to assess HRQoL. Evidence on validity, reliability, acceptability and consistency were not reported for either PROM. The psychometric evaluation only concentrated on responsiveness using univariate comparisons and multivariate analysis, neither of which was suitable for assessing the responsiveness of the PROMs.

The CAS specific PROM was developed by Ivanova et al.[23] The initial version was based on generic and neurovascular specific HRQoL questionnaires. This was reviewed by patients with CAS and clinicians. The final draft included 17 domains each with four choices. The PROM was assessed in 120 patients with asymptomatic CAS, one to three days before CEA and six to seven months after that. The authors reported improved physical, functional, psychological and social function but these were not statistically significant. Furthermore, many domains had floor/ceiling effects of more than 28.5% raising questions regarding the relevance of some of the questions included in this PROM.

Hsu et al[22] assessed the effect of CS on HRQoL in patients with CAS suffering with dizziness. Of the 178 patients who underwent CS, only 61 complained of dizziness. HRQoL was assessed using SF-36 and DHI. The SF-36 showed evidence of internal consistency (Cronbach's alpha score >0.70) but the statistical assessment of responsiveness was based on non-parametric measures and no evidence was presented regarding the completeness of the data for each of the domains.

4. Discussion

This review identified six PROMs in five studies[19-23] that reported details on the development and/or validation of PROMs for use in patients with CAS undergoing revascularisation. The quality of the instruments was variable with respect to their development and psychometric properties. None of the identified PROMs had undergone rigorous psychometric validation in patients undergoing carotid artery revascularisation. Validation of basic psychometric criteria such as construct validity and test-retest reliability had not been undertaken. Only one study, Hsu et al[22] attempted to assess the internal consistency of SF-36 although the methodology they used was questionable. Based on the findings of our review it is not possible to recommend a PROM for use in patients with CAS undergoing revascularisation.

The strength of the review lies on our comprehensive and extensive search strategy which was used to identify relevant studies. In addition, to minimise bias two reviewers undertook the screening, data coding, data extraction and psychometric analysis of all the studies, and the review covered all types of study designs. The methodological quality assessment criteria were developed from published studies as per FDA PROMs development guidance.[2] However, there are a number of limitations to our review which warrant caution to its application. The patient population included in this systematic review were heterogeneous in terms of the type of CAS, the stage of disease, and treatment pathway. For example, the Quality of life for carotid artery disease scale, reported by Ivanova et al[23] was developed in a Latvian population and the PROMs reported in Hsu et al (DHI and SF-36)[22] underwent validation in a Chinese population. As a result, the application of the findings from these studies to English speaking people is uncertain due to language validation and cross-cultural adaptation of PROMs.[11] It is important to note that these limitations are principally sourced in the evidence base, rather than the methods used to interrogate and evaluate it.

It is recommended that PROMs data is collected and evaluated as part of randomised controlled trials (RCTs) and service analysis.[3;24-26] Evidence from this review shows that most PROMs used in previous carotid trials lacked validation. Another tool occasionally used to assess functional HRQOL outcomes following CS or CEA in clinical trials is the modified Rankin scale[27] (a functional assessment scale for assessing handicap in stroke patients).[28] However, the Rankin score was not included in this review as it does not capture a patient's subjective perception of their QoL, and thus cannot be considered to be a true PROM.[29] The benefits of supplementing clinical outcome data with a well-developed, valid, consistent, reliable and responsive instrument could help provide more targeted data on aspects such as how patients feel after specific interventions, treatment efficacy, and identification of patients most likely to benefit from the procedure. Particularly since the intervention procedure is frequently done in patients who might be asymptomatic. Hence, having a universal accepted PROM measure for assessing QoL in patients undergoing carotid revascularisation will be valuable to the patients, clinicians and decision makers to guide them in providing an efficient and cost-effective treatment plan.

Some of the issues noted in this review maybe addressed by either developing a disease-specific PROM or developing a set of questions specific to CAS which can be added to complement a generic PROM (e.g. SF-36 or EQ-5D) as recommended by regulating bodies.[6] However, when developing a PROM questionnaire it is important to use qualitative methods involving patients and clinicians and insure the questionnaire captures both the breadth of the patient experience and the instrument to be reliable, valid, responsive and acceptable to patients. The questionnaire should be easy to administer and attention should be given to its format, setting and time required for completion. In addition, research exploring how to

integrate PROMs into the patient pathway needs to be undertaken, including when and at what time-points should the PROM be administered.

5. Conclusion

This review highlights a lack of evidence for valid, reliable, responsive and acceptable PROMs for use in patients undergoing carotid artery revascularisation. As a result, the development and validation of a new PROM for this patient population is warranted in order to provide data which can supplement traditional clinical outcomes (stroke<30 days post-procedural, myocardial infarction and death) and capture changes in health status and quality of life to help inform treatment decisions.

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Conflicts of interest

The authors declare no conflicts of interest.

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