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Health Economics & Decision Science (HEDS) Discussion Paper Series

Patient reported outcome measures in patients with abdominal aortic aneurysms: a systematic review protocol

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No. 16.04

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ABSTRACT

Background:
Abdominal aortic aneurysm (AAA) is a dilatation of the abdominal aorta, which is usually asymptomatic. However, rupture of the aneurysm can be fatal or require complex surgery with potential complications, leading to a poor quality of life. Patient reported outcome measures (PROMs) are becoming increasingly important in the current era of healthcare management. PROMs are used to directly assess how patients feel or function in relation to their health condition without any interpretation. Generic, disease-specific and preference-based PROMs can be used to assess the quality of life (QoL), symptoms and functional limitations in patients with AAA including those under surveillance or undergoing endovascular or open surgery or screening. However, these tools vary in terms of their reliability, validity and suitability for use in patients with AAA in a clinical setting.

Objectives:
To identify, summarise and assess PROMs that have been administered to patients with a diagnosis of AAA including those under surveillance or undergoing endovascular or open surgery or screening.

Methods:
Key electronic databases and research registers will be searched including: MEDLINE and MEDLINE in Process, EMBASE, PsycINFO, PROQOLID, CINAHL, PROMS Bibliography (Oxford University), Web of Science and the Cochrane Library databases from inception. A two-stage search approach will be used. The first stage will utilise general terms for PROMs to identify studies. These will be retrieved and the title and abstract will be examined for additional PROM terms. Stage 2 will incorporate these terms with the preliminary search strategy and a methodological search filter. Searches will be supplemented by hand-searching reference lists of relevant reviews and included studies. Study selection, data extraction and quality assessment will be performed independently by at least 2 reviewers. All English language instruments identified as PROMs for patients with AAA will be included. Data will be extracted regarding type of PROM, methods and results. Methodological quality of included studies will be assessed using the COnsensus-based Standards for the selection of health status Measurement INstruments checklist (COSMIN) and the psychometric properties of the PROMs will be assessed on criteria based in published recommendations. Findings will be presented as narrative and tabular summaries.

Discussion:
This systematic review will identify PROMs that are used to assess QoL, symptoms and functional limitations in patients with AAA and assess their effectiveness for this population and application to clinical practice. The findings of the review will help inform a project examining the re-configuration of vascular services in the UK, and identify targets for future research.

Key words: Abdominal aortic aneurysm, Patient reported outcome measures, PROMs, quality of life

Background

Abdominal aortic aneurysm (AAA) is a dilatation of the abdominal aorta, which is usually asymptomatic. However, some people may develop pain or a pulsating feeling in their abdomen or persistent back pain. Larger aneurysms (> 55mm) are at an increased risk of rupture resulting in massive internal bleeding and an extremely high mortality rate or complications resulting in poor quality of life.[1] Around 8 out of 10 people with a rupture either die before they reach hospital or do not survive surgery. The risk of AAA increases significantly after the age of 60 [2] and men are four to six times more likely than women to develop AAA.[3] However, women can also be at risk, particularly those with a history of smoking or heart disease. The prevalence of AAAs is estimated at 1.3-12.7% in the UK [4]but has been declining since 2000.[5] Depending on the size of the aneurysm, the main treatment options for patients with AAA are surgical procedures (open repair or endovascular repair) or monitoring, with better treatment outcomes in those with early detection of the disease. As patients with AAA are mostly asymptomatic screening programmes are very important in reducing the mortality and morbidly rate.

Patient reported outcome measures (PROMs) relating to symptoms, functional or health related quality of life (HRQoL) are obtained directly from the patient. These outcomes can be used to obtain information about morbidity and 'patient suffering', and can be used to assess the quality of life (QoL) of patients. PROMs are valued by patients, clinicians, and policy-makers as they provide information that supplement clinical outcomes and help to inform disease management practices, therapeutic choices, reimbursement decisions, and health policy. The current evidence regarding those PROMs used to assess the QoL of patients with AAA (including those under surveillance or undergoing endovascular or open surgery or screening) in a clinical setting is equivocal, in terms of their reliability, validity and suitability for use.

Aims and Objectives

The aim of this review is to (i) systematically identify PROMs that have been administered to patients with AAA (ii) to identify PROMs which have been validated in patients with AAA (iii) to evaluate the psychometric properties of PROMs which have been validated in this patient group using the COnsensus-based Standards for the selection of health status Measurement INstruments (COSMIN) [6](iv) and using the findings to inform the development of the Electronic Patient Assessment Questionnaire-Vascular(ePAQ-VAS) system for use in vascular services.

Methods

This systematic review will be conducted and reported in accordance with the Preferred Reporting Items for Systematic Reviews and Meta-Analyses (PRISMA) statement.[7]

Literature searching

Key electronic databases and research registers will be searched including MEDLINE and MEDLINE in Process, EMBASE, PsycINFO, PROQOLID, CINAHL, PROMS Bibliography (Oxford University), Web of Science and the Cochrane Library databases from their dates of inception. A two-stage search

approach will be used. The first stage will utilise terms for PROMs, QoL and abdominal aortic aneurysm to identify studies reporting PROMs in patients with AAA. These will be retrieved and the title and abstract examined for additional PROM terms. Stage 2 will incorporate these terms with the preliminary search strategy and a methodological search filter for finding studies on measurement properties.[8] The search strategy will be developed by an experienced information specialist in consultation with methodological and topic experts, if necessary, the search strategy will be adapted within different databases. No language or date restriction will be applied. Searches will be supplemented by hand-searching reference lists of included studies, relevant reviews and citation searches. All retrieved records will be imported and managed within a reference management database.

Eligibility criteria

Published or unpublished full-text journal articles including structured abstracts evaluating the use or validation of PROMs capturing QoL, health status or functional limitation in patients with AAA will be considered. The population of interest are patients with a diagnosis of AAA undergoing any treatment (medical or surgical) for AAA including screening. No date restriction will be applied but only studies published in English language will be included. In addition, studies that are published in English that report non-English translations of relevant PROM instruments or PROMs elicited from non-English speakers will be excluded. The outcomes of interest are PROMs (including generic, disease-specific, preference-based, functional and symptom-based) used in patients with AAA (including those under surveillance or undergoing endovascular or open surgery or screening).

Study selection

At least two reviewers will screen all references according to the agreed pre-specified eligibility criteria (see Table 1). After sifting of titles and abstracts from both searches, all full-text articles of potentially relevant studies from the retrieved records will be obtained for detailed examination. Ineligible studies will be excluded and the reason for rejection will be recorded. Disagreements between the two reviewers will be resolved by discussion, with the involvement of a third reviewer where agreement cannot be reached. The PRISMA template will be used to produce a flow chart showing details of studies included and excluded at each stage of the study selection process.

Table 1: Eligibility criteria

Inclusion criteria	Exclusion criteria
Type of participants	
A defined population of participants with a diagnosis of AAA	Unspecified population of AAA patients Patients with pseudoaneurysms Patients with thoracic aortic aneurysms, involving the aortic root, ascending aorta, aortic arch or descending aorta. Patients with thoracoabdominal aneurysms
Type of intervention	
Screening	
Any Treatment: Emergency, elective or supportive treatment including open surgery, endovascular aneurysm repair, medical treatment	
Type of outcomes	
PROMs obtained using any of the following methods:	
- generic preference-based measures e.g. EQ-5D, SF-36	Outcome measures of patient satisfaction or experience in the relevant population
- directly elicited preference-based measures e.g. TTO, SG utility values	Non-English versions of relevant PROMs
- condition-specific outcome measures	PROMs elicited from non-English speakers
- functional limitations or symptom-based measures	
- English version of PROMs	
Type of study	
Published or unpublished peer reviewed journal articles including full-text or structured abstract	Reviews, Editorial and Opinion pieces
Language	
English	Non-English

Abbreviations: AAA, abdominal aortic aneurysm; EQ-5D, European quality of life questionnaire -5 dimension; PROMs, patient reported outcome measures; SF-36, Medical Outcomes Study 36-item short form Health Survey; SG, standard gamble; TTO time-trade-off.

Data collection process

Two reviewers will independently extract data from the studies using a specifically designed data extraction form. The form will be piloted on a sample of two randomly selected studies and then altered if required before full data extraction begins. Discrepancies will be resolved by discussion, with the involvement of a third reviewer where necessary. Authors will be contacted in order to

obtain any missing data. In the case of double publication of the same study, data will be combined as a single study.

Data items

Data extraction will be undertaken in two stages. The first stage will involve abstracting data from all included studies and will aim to identify all PROMs used in patients with AAA. From the abstracted data two sets of studies will be identified:

(1) SET 1 studies: Studies reporting PROMs (generic, disease-specific, both preference based and non-preference based measures, functional limitations and symptoms) in patients with AAA.

(2) SET 2 studies: Studies reporting on the development and/ or validation of PROMs – to assess suitability of the PROM(s) for clinical/research use.

In the first stage general information regarding, study characteristic, population characteristic and outcome measures will be extracted, including the aim of the study, details on whether the study addresses the development and/or validation of a PROMs, treatment strategy and type of outcome measures used.

In the second stage, a more in-depth data extraction will be undertaken for studies in SET 2, to help evaluate the psychometric performance of reported outcome measures. Data will be extracted to assess the quality of the studies, identify the likely areas of quality of life affected by the condition and assess the overall performance of the outcome measures; for example regarding type of instrument, sample, number of items and domains, suitability of the tool for the condition, including practicality, sensitivity and validity.

Quality assessment:

Two researchers will independently assess the methodological quality of the included studies against the COSMIN checklist [6]and using the criteria in Table 2 for assessing the performance and psychometric properties of the validated PROMs identified. Any discrepancies will be resolved by consensus and if necessary a third reviewer will be consulted.

Table 2: Appraisal criteria for assessing the psychometric properties of patient reported outcome measures

Domain	Criteria
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. [6] 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.[9]
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.[6;9;10]
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.[6;10;11]
Criterion validity	A good argument should be made as to why an instrument is a gold standard and correlation with the gold standard should be ≥ 0.70.[11]
Responsiveness	There are a number of methods to measure this including t-tests, effect size, standardised response means or responsiveness statistics Guyatts' responsiveness index. There should be statistically significant changes in score of an expected magnitude.[12]
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.[11]
Acceptability	Acceptability was measured by the completeness of the data supplied. 80% or more of the data should be complete.[10]

Strategy for data synthesis

The psychometric properties of the PROMs identified will be described and evaluated using a set of standardised criteria taken from a number of published studies.[6;9-12] From the findings, PROMs, if any, that are ready for clinical use or which need further work will be highlighted and discussed. For studies that do not report development or validation of PROMs in AAA, a tabular narrative synthesis will be undertaken, structured around the type of PROM identified (generic, disease-specific, preference based, functional, symptom), the domains each PROM measured, characteristics of participants and treatment strategy.

Discussion

PROMs are a valuable tool to clinicians and decision makers to guide them in providing an efficient and cost-effective treatment plan for patients. To date there has been no systematic reviews reporting PROMs that have been used to assess QoL, symptoms or functional limitations in patients with AAA. It is unclear regarding the evidence for the validity of PROMs in this patient population or evaluated their suitability for use in this group. We plan to use a systematic approach with a comprehensive search strategy to identify PROMs that have been used in patients with AAA (including those under surveillance or undergoing endovascular or open surgery or screening), and assess its psychometric properties and suitability for use in this population.

Strengths and limitations

The strength of our review lies on the comprehensive two step search strategy which will be used to identify studies. The search strategy will be developed by an experienced information specialist in conjunction with a multi-disciplinary team of clinical and methodological experts. In addition two reviewers will undertake the screening, data coding and data extraction of all the studies. Our results may be limited due to the decision to exclude studies published in non-English language, non-English version of relevant PROMs and PROMs elicited from non-English speakers. However as this review is undertaken to inform a project[13] examining the re-configuration of the vascular services in the UK, it is vital for the evidence base to reflect its users.

Relevance of the review

The findings of this review will enable us to identify PROMs which are or are not appropriate for clinical use in patients with AAA (including those under surveillance or undergoing endovascular or open surgery) within the vascular services in the UK, and highlight the gap in the evidence base for further research. Furthermore, findings from this review will be supplemented by qualitative evidence to inform the development of ePAQ-VAS system for use in vascular services.

Dissemination plans

We will disseminate our findings in a report to the NIHR, conferences proceedings and peer-reviewed journal publications.

Funding

Source of funding for research: This research is funded through the National Institute for Health Research Programme Grant (Project ID: RP-PG-1210-12009)

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