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Health Economics & Decision Science (HEDS)

Discussion Paper Series

Understanding the experience and impact of living with a vascular condition from the patients perspective: a qualitative evidence synthesis protocol

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Title: Understanding the experience and impact of living with a vascular condition from the patients perspective: a qualitative evidence synthesis protocol

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Abstract

Background: Patient reported outcome measures (PROMs) provide a way of measuring outcomes elicited directly from the patient. It is important that PROMs cover the domains that are important to patients. This can be achieved by conducting qualitative research studies looking at patient experiences.

Objectives: The aim of this qualitative evidence synthesis will be to examine the symptoms and quality of life domains that are important from the perspective of the patient with peripheral arterial disease (PAD), abdominal aortic aneurysm (AAA), carotid artery disease (CAD), varicose veins (VV) and venous leg ulcers (VLU).

Methods: Searches will be conducted in CINAHL via EBSCO, MEDLINE and MEDLINE in Process via Ovid, EMBASE via Ovid, PsycINFO via Ovid, Social Science Citation Index/ Science Citation Index via Web of Science (Thomson Reuters) and Proquest dissertations and theses to identify primary qualitative studies reporting on patients' health or QoL for the 5 vascular conditions. The methods of each study will be assessed for quality using the CASP criteria, *10 questions to help you make sense of qualitative research*. Data will be extracted and synthesised using a framework analysis in Nvivo.

Discussion: This qualitative evidence synthesis will identify studies that are qualitatively exploring health and QoL life outcomes for people with one of the 5 conditions to inform the selection of patient reported outcome measures and identify targets for future research. This

review forms part of a larger project concerned with selecting PROMs for use in vascular services.

Key words: Peripheral arterial disease, abdominal aortic aneurysm, carotid artery disease, varicose veins and venous leg ulcers, patient reported outcome measures, PROMs, quality of life, QoL

Background

In the UK, 5 vascular conditions are commonly treated by the National Health Service's (NHS's) secondary service services; AAA, PAD, CAD, VV and VLU. Understanding the symptoms and quality of life (QoL) of patients with these conditions is important for understanding the impact of the service on outcomes other than morbidity and mortality. In other conditions treated by the NHS routine collection of patient reported outcome measures (PROMs) has been implemented (1). It is recommended (2) that PROMs be developed by consulting patients to cover the health and QoL concepts that they find to be important, to ensure that the full breadth of the condition is captured.

Aims

The aim of this literature review will be to examine the symptoms and quality of life domains that are important from the perspective of the patient with PAD, AAA, CAD, VI and VLU. This research forms part an NIHR programme grant concerned with selecting PROMs for use in vascular services (3).

Methods

Search Strategy

Searches will be conducted in CINAHL via EBSCO, Medline and Medline in Process via Ovid, Embase via Ovid, PsycINFO via Ovid, Social Science Citation Index/ Science Citation

Index via Web of Science (Thomson Reuters) and Proquest dissertations and theses. No language or date constraints will be applied. To identify relevant evidence for the qualitative literature review a search strategy will be developed to include condition terms, terms for patient reported outcomes/patient views and terms for qualitative studies. Free text and thesaurus terms (such as MeSH) will be combined using Boolean operators. The search will be based on the search strategy created for the related reviews of PROMs for the respective conditions. A qualitative study filter will be used and combined with relevant thesaurus terms for qualitative studies (4). The reference list of included full text studies will be scanned for relevant studies and the studies citation checked.

Eligibility criteria

Qualitative studies will be included if they report on people's health, quality of life or experience of people living with one of the 5 vascular conditions. Studies will be included with a defined population of PAD, AAA, CAD, VV or VLU (further details of the condition inclusion exclusion criteria are listed in table 1) and that include semi-structured interviews, descriptions, focus groups as stand-alone studies or that are embedded in a quantitative study. The reports should have written evidence of both the data collection process and data analysis. This will include reports from either patients or clinicians of both published and unpublished works. Studies will be excluded if they are not reported in English; if the participants were under 16 year of age; if no primary qualitative data was reported and if the published or unpublished full-text or structured abstract provided incomplete or unclear evidence. The inclusion and exclusion criteria are also presented in table 1.

Table 1: Summary of the inclusion and exclusion criteria for the qualitative reviews of 5 vascular conditions.

Inclusion	Exclusion
Patient's health, health related quality of life, or experience of one of the 5 vascular conditions listed below	Studies not in English
Clinicians views	Studies with participants under 16 years of age
Peripheral Arterial Disease (PAD) A defined population of participants with a diagnosis of PAD, also described as: peripheral vascular disease, peripheral obliterate arteriopathy, peripheral arterial occlusive disease OR patients with clinical evidence of any or a combination of the following, where PAD is the confirmed or stated underlying cause: rest pain, claudication, vascular spasms, ischaemic ulceration, necrosis or gangrene of the limb amputation	Undefined population of PAD patients and patients with claudication, lower limb ulcers or amputations due to any cause other than PAD
OR **Abdominal Aortic Aneurysm** (AAA) 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
OR **Carotid Artery Disease** (CAD) A defined population of participants with a diagnosis of CAD who need, have had or are undergoing invasive procedures. Participants undergoing treatment for stroke or transient ischaemic attack (TIA) secondary to a diagnosis of CAD	Unspecified or mixed populations which include CAD patients. Patients with Stroke or TIA not related to CAD
OR **Varicose Veins** (VV) a defined population of participants with a diagnosis of chronic venous insufficiency (CVI) presenting with varicose veins	An undefined population of CVI patients or patients with acute venous obstruction, such as acute deep vein thrombosis.
OR **Venous Leg Ulcers** (VLU) A defined population of participants with a diagnosis of chronic venous insufficiency (CVI)presenting with venous leg ulcers, oedema or skin discolouration	An undefined population of CVI patients or patients with acute venous obstruction, such as acute deep vein thrombosis.
Studies that include semi-structured interviews, descriptions, focus groups either as stand-alone studies or embedded in a quantitative study. Must include both data collection and data analysis	Quantitative studies with no primary qualitative data reported
Published or unpublished; full-text or structured abstract with all relevant information	Published or unpublished; full-text or structured abstract with incomplete or unclear evidence

Study selection

The search results will be entered into Reference Manager 12 and duplicates will be removed. Titles and abstracts will be screened for the inclusion and exclusion criteria by one reviewer. Full texts will be retrieved for relevant studies and read in full. Studies that do not meet the inclusion and exclusion criteria will be excluded. Full data from the included studies will be extracted to create a comprehensive dataset of studies.

Critical appraisal

The Critical Appraisal Skills Program (CASP) instrument will be used to assess the methodological quality of each of the articles included in the review (5). This was selected as it assesses both the appropriateness and the quality of reporting of the studies included and is commonly used in qualitative reviews of evidence (6).

Data extraction

A data extraction form will be designed in Microsoft Excel 2010 to include the following items: Author, year, country, research design, purpose of the study, sample size, diagnosis, eligibility criteria, age (mean), gender (% male) and the main findings (describing the understandings of the participants). It is expected that the data extraction form will be modified following pilot testing.

Data synthesis

As the aim of the study is to identify and extract data on the aspects of health and QoL of the five different vascular conditions that will in time be used to triangulate with other data sources to create an electronic PROM (ePROM) it would seem appropriate to use an inductive process of framework analysis using method of best fit (7,8) as PROMs used for each condition will be identified in separate reviews and their conceptual domains will have been mapped to give a basis for the qualitative data analysis. Text will be coded into the domains identified from PROMs in the literature and additional codes added for concepts not

previously captured. Text that cannot be easily coded into an existing theme will be put into a category of "Other". A team of researchers will then review the other category and either fit them into the existing themes or inductively create new themes for the text.

Articles will be uploaded into NVIVO v10 for management and analysis. Following a framework analysis approach the reviewer will begin by familiarising themselves with the content of each study. They will then systematically read each article in full and code any extracts where participants have discussed aspects of health or QoL for each of the 5 conditions and whether they have been reported by patients, clinicians or researchers. These codes will add and expand on the domain framework identified in reviews of PROMs for the respective vascular conditions. Once thematic saturation has been achieved the verbatim text extracts will be added into a framework matrix.

Discussion

To our knowledge there has been no previous review of the qualitative literature for any of the vascular conditions. Understanding the health and QoL outcomes that are important to people with a condition are important in directing whether a treatment is making the desired changes and guiding clinical practice. In selecting a PROM for use in research or clinical practice it is important to capture the full breadth of a patient's experience of a condition. A review of the qualitative literature can examine the literature for previous studies of patient's experiences.

Strengths and limitations

The review will allow previously identified themes to be included. The searches will be carried out by an information specialist and at least two reviewers will perform the sifting and extract the information from the included studies. The analysis will be guided by a multi-disciplinary team of methodological and clinical experts. The inclusion of studies conducted in another language and reported in English could result in misinterpretations of the original

meaning in the translation process. This should be considered when interpreting the results of the review and in reporting the findings.

Relevance of the review

The themes identified in the review will help to inform the selection of PROMs for clinical use in patients with AAA, PAD, CAD, VI and VLU's. They will identify where there are gaps in evidence. The themes will later be triangulated with the themes identified from qualitative interviews and a Delphi study.

Dissemination plans

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

Funding

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