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Electronic personal assessment questionnaire for vascular conditions (ePAQ-VAS): development and validity.

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Abstract:

Background: This paper describes the development and validation of an electronic personal assessment questionnaire for vascular conditions (ePAQ-VAS) that captures symptomatology, quality of life and clinically relevant data to patients presenting to vascular services.

Methods: A two-stage survey was conducted in patients attending a tertiary vascular department. Patients completed the ePAQ-VAS questionnaire remotely online or on site using an electronic tablet. In the first stage of the survey the responses were used to perform confirmatory factor analysis to assess the construct validity and remove redundant items. The internal reliability of disease-specific scales was investigated. In the second stage of the survey, the acceptability, known-group validity, test-retest reliability and responsiveness of ePAQ-VAS was assessed.

Results: In total, 721 patients completed ePAQ-VAS, the mean age was 63.5 years (15.7 SD); 64.9% were men (468); 76% of patients (553) completed the questionnaire in clinic and the remaining patients completed the questionnaire online. The results of the confirmatory factor analysis confirmed the conceptual model for ePAQ-VAS structure and eliminated six items. Internal reliability was acceptable for all the scales (Cronbach's alpha >0.7). The test-retest reliability measured by the intraclass correlation coefficient ranged from 0.65-0.99. The results showed that the instrument is responsive over time with standardised response mean ranging from 0.69-1.60.

Conclusions: ePAQ-VAS is a holistic data-collection process that is relevant to vascular service users and has potential to contribute to patient-focussed care and the collection of aggregate data for service evaluation.

Introduction

Clinical outcomes in patients undergoing procedures for vascular diseases have been the focus for vascular services evaluation in the United Kingdom **(1).** These clinical outcomes, include technical measures such as patency and pressure indices or functional issues such as walking distance, may be a poor proxy for the effect of a condition on any patient. The use of these outcomes only reflects the impact of vascular disease and treatment on the small proportion of patients that develop adverse clinical outcomes **(2)**, they do not measure the impact of vascular disease and treatment among many other patients, including those treated conservatively **(2,3).**

In response to this problem, several condition-specific and generic patient-reported outcome measures (PROMs) have been developed or assessed for use in specific vascular conditions. These include condition-specific PROMs can capture aspects of disease important to patients and provide a picture about the impact of the disease on health-related quality of life (HRQoL) **(4, 5)**, whereas, generic measures can be used to capture benefits across different conditions and treatments **(5).** PROMs can be used for diagnosis, monitoring, and measuring treatment effects, especially when integrated into an electronic patient record (EPR) platform **(6).** Increasingly, PROMs are being used to calculate quality adjusted life years for use in cost-effectiveness analysis of health and care interventions.

The regular use of PROMs in clinical practice can guide treatment choice, shared decision making, and self-management. Evidence also suggests that clinicians can provide improved patient-centred care when PROMs are integrated into disease registries, where outcomes are tracked over time **(6).** However, the use of these measures to assess the impact of vascular conditions is limited to clinical studies and rarely used for patients' assessment and service evaluation **(7-11).** This is in part because most vascular patients present with overlapping symptoms or mixed conditions, furthermore, logistically, it is difficult to use paper-based PROMs to monitor patients with chronic and recurrent vascular conditions **(12-15)**.

Hence, as part of the National Institute of Health Research (NIHR) programme considering the configuration and monitoring of vascular services, a new vascular PROM was developed. This new electronic tool followed the successful models in which electronic PROMs were used for patients' diagnosis, assessment, and long term monitoring **(16).**

The electronic patient assessment questionnaire for vascular patients (ePAQ-VAS) was developed in line with internationally recognised standards and guidelines **(17-19)**. It captures the impact of five main vascular conditions; abdominal aortic aneurysm (AAA), peripheral arterial disease (PAD), carotid artery disease (CAD), varicose veins (VVs) and venous leg ulcers (VLU). The decisions to only include these conditions was based on systematic reviews and a clinicians' consensus exercise **(7-11,**

20). The advantages of this electronic tool are that it can be integrated into an EPR and facilitate focused consultations as patients can complete the questionnaire before the clinic appointment. Patients can complete the questionnaire on mobile phones or computers, and remote completion can facilitate virtual clinics. Furthermore, the electronic data generated by patients can help long term monitoring of disease, service evaluation, and linkage to other data. Lastly, this electronic tool incorporates skipping rules removing the need for patients to complete irrelevant sections.
The aim of this paper is to present the steps taken to develop and the validate ePAQ-VAS.

Methods

The conceptual framework for the ePAQ-VAS questionnaire was developed from three distinct sources to identify the key issues, symptoms and the impact of AAA, PAD, CAD, VLU and VV on patients with these conditions. First, systematic literature reviews of existing outcome measures and qualitative evidence were conducted **(7-11, 21-24)**. Second, clinicians involved in the care of vascular patients were invited to list the key issues, symptoms and the impact of these conditions **(20)**. Third, semi-structured interviews were conducted with five vascular patient groups PAD, AAA, CAD, VLU and VV. Users of vascular services attending the vascular department, Sheffield Vascular Institute (SVI) at the Sheffield Teaching Hospitals were recruited for this study purposive sampling techniques to ensure a range of participants at different age, sex and stages of treatment. Patients were asked about their symptoms, impact of the condition on their functioning and lifestyle. Framework analysis was used to study the qualitative data from the interviews and six overarching themes were identified for patients with PAD, AAA, CAD, VLU and VV. These were symptoms (including pain), impact on physical function, social impact, psychological impact, financial impact and lifestyle. **(25)**.
The themes identified above were used by the ePAQ-VAS steering committee (SCR, GJ, PP, EL, AA) to generate items (questions) for the initial item pool **(see *supplementary material Appendix 1*)**.
The list of items was presented first to 13 clinicians involved in the care of vascular patients who were invited to score the relevance of items in the provisional version of ePAQ-VAS and suggest new items **(20)**. Second, to ensure face validity, interviews were conducted with 19 patients, purposefully sampled from vascular populations previously described. Inputs from clinicians and service users were used to revise the questionnaire by deleting 59 items, adding 5 items and rephrasing 12 items.
The resulting ePAQ-VAS had 114 items and these were divided into sections, including a generic section asking about common vascular symptoms, relevant medical conditions, medications, clinically relevant questions (e.g. smoking, weight, diabetes) and screening questions to ensure only relevant questions are presented to the patients based on their specific vascular complaint. There were three

disease specific sections including AAA, CAD and lower limbs sections. In these disease-specific sections there were eight scales with 55 items. The eight scales were CAD related anxiety, impact of CAD on activities of daily living (ADL), AAA related anxiety, impact of AAA on activities of ADL, PAD symptoms, VLU symptoms, VV symptoms and impact of lower limb vascular disease on ADL. For an overview of the development process see Figure 1.

Insert Figure 1 here

Item reduction and internal reliability

Participants' recruitment

To reduce the burden of ePAQ-VAS, statistical analysis of the results of a survey was done to delete questions from ePAQ-VAS that were redundant. Consecutive patients attending outpatient clinics run by SVI between June 2017 and June 2018 were invited to complete the questionnaire online before their clinic appointment or onsite using electronic devices. Onsite, patients could complete questions and ask for technical help from researchers. The five key vascular conditions identified (AAA, CAD, PAD, VLU and VV) were all represented in the sample.

Statistical analyses

Sample-size calculation was based on previous studies suggesting a required ratio between 4 and 10 respondents per item to enable factor analysis and internal reliability calculations **(26,27)**. Based on 55 items within ePAQ-VAS contributing to eight scales, up to 550 patient completions were considered necessary.

Item reduction

One-factor confirmatory factor analysis (CFA) model for ordinal data **(28)** was fitted to each of the eight scales to test whether the empirical data supported the eight scales identified in the conceptual framework, The results of the analysis were also used to reduce the number of items. Appropriateness of the CFA model for each scale was assessed by examining the comparative fit index (CFI) and the root mean square error of approximation (RMSEA), where CFI >0.95 and RMSEA < 0.08 were regarded as appropriate fit **(29)**. Furthermore, item factor loadings (>0.4); model residual correlations and modification indices were considered to examine local dependence within domains **(29)**. For these three indices, their magnitude was evaluated in comparison to other items in the scale; when the modification indices (MI) were >100 and residual correlations (RC) >|.10| this was taken as the indicator of lack of fit and items were removed from the scale**(29)**. Redundant items were removed using the results from the CFA. MPlus version 8.2 (Muthen & Muthen, Los Angeles, California, USA) was used for the statistical analyses **(30)**.

Internal consistency

To assess whether each scale within ePAQ-VAS was measuring what was intended cronbach alpha coefficient was calculated to measure internal consistency reliability. A Cronbach's alpha score of ≥ 0·70 was considered acceptable, however scores exceeding 0·92 were taken to indicate that items in the scale may be redundant **(18, 31)**.

ePAQ-VAS acceptability, validity, reliability and responsiveness

The results of relevant items from the above survey and an additional survey were used to validate the measure by examining acceptability, test-retest reliability, construct validity, and the responsiveness of the measure.

Participants' recruitment

All consecutive patients invited to outpatient clinics run by the SVI from June 2018 to January 2019 were asked to participate in this study. For test -retest reliability, patients were asked to complete a second questionnaire three to seven days later, provided there was no change to their health status. Only patients with AAA, PAD, VLU and VV were included in this survey as CAD patients were only available prior to revascularisation procedures. To assess responsiveness, patients completed ePAQ-VAS before, and six weeks after PAD and VV procedures. The second survey for test-retest reliability and responsiveness was completed over the telephone by one of the researchers.

Statistical analyses

Acceptability

Acceptability of ePAQ-VAS was measured by examining the completeness of the data. Good level of acceptability is confirmed if 80-95% of the data are completed by the patients **(31).** Additionally, the mean and median of time taken to complete this instrument online or in clinic was calculated.

Scoring

A summative score for each the eight scales in ePAQ-VAS was calculated and standardised to a 0-100 scale, where 0 indicates the best, and 100 the worst, outcome. Skipped items were allocated a score of zero, as the questionnaire allows skipping of sections and individual questions that are not of relevance.

Test-retest reliability

Intra-class correlation coefficients (ICCs) were used to assess test-retest reliability. ICC exceeding 0.7 are generally regarded as reliability for population-based research and ICCs exceeding 0.9 are considered to indicate reliability for use clinically with individuals **(32)**.

Known-group validity

Known group validity was examined using hypothesis testing to examine whether the scales correlate well with expected clinical group differences. Correlations are considered low if $r < 0.3$, moderate if r lies between 0.30 and 0.49 and high if $r < 0.5$(15). Hypotheses were stated *a priori*, including the

postulated direction **(17, 33)**. The clinical hypotheses proposed that the CAD anxiety and ADL scale scores would be higher (worse) for patients with stroke compared to those presenting with TIA. The AAA scale scare would be higher with patients with larger aneurysms and patients with ulceration or rest pain and PAD would have worse score than PAD patients with claudication. For the list of these hypotheses for each condition, **see supplementary Appendix 2.**

Responsiveness

Responsiveness was measured using standardised effect size, calculated as change of score between post-operative patient score and pre-operative score divided by standard deviation at baseline. An effect size of 0.30 – 0.50 is regarded as 'small', 0.50 – 0.80 as 'moderate', 0.80 and above as 'large' **(33)**. Standardised response mean was also calculated as the mean difference between baseline and post-intervention divided by the standard deviation of the change, and classified using the same criteria**.** Statistical analyses were performed using SPSS (IBM, New York, USA) Version 24.

Results:

The response rate for patients invited to complete the questionnaire online prior to attending their clinic appointment was 24.2%. In total 721 patients completed ePAQ-VAS, their mean age was 63.5 (15.7 SD). 64.9% were men (468); 76% of patients (553) completed the questionnaire in a clinical environment (clinic or ward) and the remaining patients completed the questionnaire online. The mean time to complete ePAQ-VAS in the clinic was 12:51 minutes (Median, 09:14 minutes) and online prior to the clinic appointment was 36:51 minutes (Median 30:44 minutes), the difference in completion time is likely due to availability of help from researchers in clinics to complete ePAQ-VAS. ePAQ-VAS showed good acceptability with 350 item responses missing from 56,238 (0.62%). The final scores were calculated for each scale and presented in Table 1.

Insert table 1 here

Item reduction

The eight scales within the condition-specific sections of ePAQ-VAS were identified through qualitative evidence from patients and clinicians. The responses of patients from the first survey were used in the CFA models to examine whether this structure was supported empirically. In the CAD section two scales were modelled and all items within the "CAD related anxiety" supported the latent factor. However, two items were dropped from "Impact of CAD on ADL" domain. The first was a generic item about the impact of CAD diagnosis on enjoyment of life, this item had high MI and RC with other items

in the same scale. The other item deleted from this scale asked about impact on mood and this had low factor loading. In the AAA section, only one item asking about the impact of AAA on enjoyment of life was deleted, this item had high MI & RC with items in the same scale. A similar item asking about impact of lower limb symptoms on enjoyment of life was also dropped because high MI and RC with other items within the same scale. In the lower limb section two further items were dropped from the final version of ePAQ and these were asking about "cold feet" and VLU symptom, both items had low factor loading. For further details about the CFA models results, factor loading and other parameters please see **supplementary material Appendix 3**.

A demonstration version of the final version of ePAQ can be viewed at: http://demo-questionnaire.epaq.co.uk/home/project?id=aaa_1.0&page=1

Internal reliability

After dropping six items based on the results from the CFA, the internal consistency of each scale was examined, and all scales had a Cronbach's alpha coefficient ≥ 0·70 and none exceeded 0·92. For further details please supplementary material appendix 3, table 5 .

Test-retest reliability

For the test-retest survey 150 patients (60 with PAD, 39 with VLU and 51 with VV), completed the relevant sections of a second questionnaire after 3-7 days. Test-retest results were calculated for the symptom scale and impact of the lower limb vascular disease on ADL for patients with PAD, VLU and VV separately. The ICC ranged from 0.65 for VV symptoms to 0.98 for the PAD and Lower Limb ADL symptoms and 0.99 for the VLU symptoms as shown in supplementary material appendix 3, table 5.

Known-group validity

The correlation between size of AAA and AAA related anxiety score was significant. There was a significant correlation between rest pain and PAD symptoms and impact of PAD on ADL. Presence of ulcer had a statistically significant correlation with the score on PAD ADL.

Ulcer recurrence had a significant correlation with VLU symptom scale score. The presence of VV in both legs had a significant correlation with VV symptoms only and the presence of VV in both legs did not have strong correlations with scores of VV ADL. Correlations between the proposed clinical

hypotheses and CAD ADL and CAD anxiety scores were low ranging from -0.089 to 0.094. This could be due to small sample size (n = 50) in the CAD group.

The results of known group validity were mixed, with some being in line with proposed clinical hypotheses, for instance the larger the size of AAA the greater the anxiety caused by the condition and the presence of rest pain or ulcer significantly impact the score of PAD scales. However, some clinical hypotheses, particularly in CAD scale scores were not in line with what was proposed (see table 2).

Insert table 2 here

Responsiveness

In total 92 patients completed the responsiveness survey, of these, 55 patients had VV procedures and 37 lower limb revascularization procedures for PAD. These patients completed the ePAQ-VAS pre-operatively and once more at least six weeks following their operation. All patients included in the analysis had successful outcomes from their procedure. The effect size and standardised response mean were measured for all the relevant scales of ePAQ-VAS to examine whether ePAQ-VAS can pick up the difference in health status following successful interventions. As shown in table 3, the effect size was moderate for PAD symptoms and large for the remaining scales. The results for the standardised response means were all moderate apart from VV being large.

Insert table 3 here

Discussion

Systematic reviews of condition specific vascular PROMs identified a lack of adequately validated tools for most vascular conditions **(7-11). T**he use of validated PROMs is limited and the data generated are rarely used in clinical decision making or monitoring of patients **(9).** The ePAQ-VAS is a tool that covers the five main vascular conditions of AAA, PAD, CAD, VVs and VLU. It has been developed in line with the FDA, the consensus-based standards for the selection of health measurement instruments (COSMIN) and other international guidelines **(17-19).** The items in this multi-sectional tool were developed based on the views of vascular patients experiencing the conditions and clinicians treating them. ePAQ-VAS was evaluated for its acceptability, reliability, validity and responsiveness in a large study involving 721 patients. The results of this study show that it has robust content and face validity and good acceptability, internal consistency, and

responsiveness. Many of the scales within the ePAQ-VAS exhibit good test-retest reliability and known group validity.

The main advantages of ePAQ-VAS are that it is a single instrument covering most patients treated by vascular services. This is particularly important for patients presenting with mixed symptoms or multiple conditions, therefore facilitating a focused, as well as holistic, approach to treat the causes of their symptoms. The electronic format of this tool makes it easier to monitor patients over time, especially those with chronic conditions and those treated with lifestyle modification or conservatively. The questionnaire can be completed before the clinic or at the clinic before meeting the clinician and can help shared decision making and enable focused consultations. The data collected cover clinical and quality of life information and can be added to the patient electronic record. This can help assess the service over time if adopted locally and nationally. Evidence suggests that when electronic tools like ePAQ-VAS are included in disease registries they can facilitate patient centred care **(6).** Another strength of ePAQ-VAS is that it generates detailed descriptions of the quality of life for people with different vascular conditions. EQ-5D is a generic outcome measure with five dimensions (mobility, self-care, usual activity, pain, anxiety and depression) that can be used to generate quality adjusted life years, a composite measure of length and quality of life, that is recommended for use in economic evaluation **(34)**. Therefore, if EQ-5D is used alongside ePAQ-VAS, utility values can be generated for the different vascular health states, which in turn can be used in economic evaluation in research settings and service evaluation in clinical settings. The disease specific data and utility values may also be used in the future to consider the relationship between such generic measures and the more detailed symptomatic and disease-specific description of vascular conditions provided by ePAQ-VAS.

There are several limitations of this study, the survey for validating this tool was conducted in a single centre. The patients completing the questionnaire were aware that they are completing it for research purposes only and that the results would not be used in their clinical consultation or management. This can be one of the reasons for the low completion rate of ePAQ-VAS prior to the clinic appointments. Previous experience with electronic ePAQ questionnaire used in other disease areas suggest that patients are more likely to complete outcome measures before their clinic appointment when it is in routine clinical use and assist in their management **(6, 35)**. Future studies are warranted to examine response rates and the discrepancy between response rates online before the clinic and at the clinic before meeting the clinicians. Furthermore, the online nature of the questionnaire meant that younger patients or those with family support were more likely to

complete ePAQ-VAS when compared to older patients and those less familiar with online technology.

There was a discrepancy in the completion times for patients completing the questionnaire online before the clinic appointment and those completing it in the clinic before their appointment with the clinicians. This could be because patients completing online were unsupervised & unsupported, completion times may have been affected by variables such as Internet connection speeds as well as interruptions or distractions, which were not measured. The presence of researchers in the clinics could have introduced bias to the results of completion time and reduced this for those patients completing the questionnaire there.

The sample size for some of the statistical analyses was small particularly for patients presenting with CAD and AAA. This was due to resource limitations of the research team and patient availability when compared to other disease groups such as PAD and VLU. The access to certain patient groups, especially for post-operative patients was limited. Fourth, the follow up data for test-retest and responsiveness were collected on the phone with the answers recorded by an interviewer. The presence of an interviewer could have introduced bias to the results and reduced completion time. Further studies can explore ways to improve data collection for follow-up data. Another area of validation of this instrument is the predictive validity and this can important for examining the ability of the questionnaire to monitor the impact of chronic vascular conditions on quality of life and the symptom change over time.

This research has resulted in the development of a new electronic instrument, the ePAQ-VAS, for the collection of patient-reported outcome data that captures symptomatology, quality of life and other clinically relevant data such as experience with NHS services and co-morbidities, experienced by most patients presenting to vascular services. Such data may contribute to electronic patient records and be invaluable in the management of individual patients and collection of aggregate data for service evaluation and research.

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