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Article type : Review

Experiences of living with varicose veins: a systematic review of qualitative research

Descriptive title: Understanding the experiences of patients living with varicose veins, and the impact on quality of life, by reviewing and synthesising qualitative research.

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Abstract

Aim: To identify the symptoms and quality of life impacts that are important from the perspective of patients with varicose veins, and to compare identified themes to items in varicose vein Patient Reported Outcome Measures (PROMs).

Background: Varicose veins are common worldwide, and are considered a chronic condition with implications for quality of life. Treatment is predominantly conservative, therefore understanding patients' experiences of living with varicose veins is important to inform the provision of clinical care. PROMs are often used to collect data about patients' quality of life.

Design: Thematic synthesis of qualitative research reported according to ENTREQ guidelines.

Methods: Multiple electronic databases, including MEDLINE and CINAHL, were systematically searched to identify qualitative research examining experiences of adults with varicose veins. Thematic synthesis was then conducted on the included studies.

Results: Three studies met the inclusion criteria; the quality of the studies was high. The range and intensity of reported symptoms and participant's experiences of living with varicose veins were varied. Five overarching themes were identified; physical, psychological and social impact of varicose veins, adapting to varicose veins and reasons for seeking treatment. The overall key theme to emerge was adaptation, with patients' demonstrating how they adapted to the various impacts.

Conclusion: This review demonstrates that varicose veins have a wide range of symptoms, and may have a significant impact on quality of life; people made significant adaptations to enable them to live their lives as fully as possible.

Relevance to Clinical Practice: Healthcare professionals need to be aware of the range of symptoms, and their impact on quality of life. The use of PROMs to gather information about quality of life and symptoms is well established globally; however, PROMs currently used may not capture the full extent of the impact on patient's quality of life.

Keywords:

Varicose veins, systematic review, qualitative research, patient reported outcome measures, PROMs, quality of life, symptoms.

Summary Points - What does this paper contribute to the wider global clinical community?

- ❖ This review identifies that there are a wide range of symptoms of varicose veins, and that symptoms can have a significant impact on patients' quality of life. It demonstrates that patients often adapt their lives in order to cope with the range of impacts that their varicose veins have.
- ❖ It highlights that a number of different instruments can be used to measure the effects of varicose veins; however, it is clear that no instrument currently captures the full impact of varicose veins on quality of life.
- ❖ Healthcare professionals need to ensure patients are fully informed of all aspects of their condition in order to help with self-management, increase adherence to compression therapy, allay unfounded fears and manage treatment expectations.
- ❖ Familiarity with the findings of existing qualitative literature through qualitative reviews, or employment of qualitative research methods such as interviews, enables an in-depth understanding of the range and severity of symptoms, and resulting impact on quality of life, experienced by patients.

Experiences of living with varicose veins: a systematic review of qualitative research

INTRODUCTION

Varicose veins (VV) are a relatively common vascular condition globally with worldwide prevalence ranging from 5-15% for men, and 2-29% for women (Health Quality Ontario (HQO) 2011). Vein problems are amongst the most common chronic conditions in North America and Western Europe (Vascular Disease Foundation 2005). Lower limb VV are estimated to be the 7th most common reason for physician referral in the United States (US), affecting an estimated 35% of the US population (HQO 2011); VV are also the most prevalent vascular condition treated by physicians in Australia (Wong 2017).

It is estimated that VV affect at least a third of the United Kingdom (UK), (Evans *et al* 2014) and up to 40% of the general population (Robertson *et al* 2016).

VV are one of a number of symptoms associated with chronic venous insufficiency (CVI) and chronic venous disease (CVD). CVI occurs when the venous wall and/or valves in the leg veins are not working effectively, causing blood to collect in the veins. The reflux of blood results in VV which become enlarged lumpy and visible, and are usually present in lower limbs.

VV cause symptoms such as throbbing pain, aching swelling, cramping, itching and bleeding (Palfreyman *et al* 2009); VV associated symptoms, and consequential restrictions on the ability to walk and stand, can have a substantial impact on patient quality of life (QoL) (Darvall *et al* 2012, Kahn *et al* 2004).

An estimated 30% of people with VV will develop skin changes such as eczema, oedema and skin discoloration, associated with CVD (Lee *et al* 2015). In addition, between 3 and 6% of people with VV will progress to developing venous leg ulcers (VLU), another chronic condition associated with CVI, (National Institute for Health and Care Excellence (NICE) 2013). Approximately 2% of UK National Health Service (NHS) resources are spent on managing venous disease (Shingler *et al* 2013), with 35,659 VV procedures carried out in the NHS in 2009/10 alone (NICE 2013).

VV can be treated conservatively, through the use of compression hosiery and lifestyle advice. Compression therapy does not actively treat CVD, it is used to manage symptoms such as swelling, heaviness and pain, and to help blood flow and venous return, thus slowing disease progression (NICE 2013). Patients should also receive advice regarding weight, lifestyle, measures to prevent symptoms worsening such as elevating legs, and the importance of skin care (NICE 2013).

However, adherence to treatment can be an issue, and the evidence base for the effectiveness of these approaches is limited (Shingler *et al* 2013). Alternatively, invasive treatments, such as endothermal ablation, foam sclerotherapy and surgery, may be required to reduce symptoms and slow disease progression.

Decisions on how, and when, to treat VV are subject to variation across the UK and are based on local interpretation of NICE guidance and referral guidelines, by regional clinical commissioning groups (CCG) (Lim *et al* 2010 and Marsden *et al* 2013). Quality of life (QoL) issues may be deciding factors in treatment decisions; therefore, understanding the effect that VVs have on QoL is important.

One method of collecting data about QoL is the use of patient-reported outcome measures (PROMs). PROMs comprise of a series of structured questions that ask patients about their health, and health-related QoL, from their point of view (Devlin and Appleby 2010). PROMs provide information about the impact of a disease, or its associated treatment, from a patients' perspective; they do not ask about satisfaction with, or experience of, healthcare services.

PROMs are used internationally by health organisations both to collect routine data to inform policy decisions, and by individual clinicians to gather patient information in order to guide clinical and shared decision-making (Black 2013). PROMs are either generic, so they can be used across different populations and health conditions, and can allow comparison between groups; or they can be disease or condition specific, containing items that are more relevant to that specific group.

PROMs are used globally, although their use is better established in countries such as the UK, the Netherlands, Sweden and the US (Williams *et al* 2016). In the US the Food and Drug Administration (FDA) recommended that PROMs should be included in all clinical trials (FDA 2009). More recently, in 2016, a commission was established in Australia to review the rationale and use of PROMs in order to help embed the use of PROMs in the Australian healthcare system (Williams *et al* 2016).

Despite the increasing use of PROMs in clinical practice it is important to note that there are limitations in their use, due to issues of validity and reliability related to the nature of self-report. Relying on patients to self-report their health can be challenging, particularly with patients suffering from cognitive deficits, paralysis or dementia, those who may not read or speak English, or those that are not literate (children and babies). Proxy versions of PROMs (e.g. that can be completed by caregivers) and PROMs designed for completion by specific groups, such as children, do exist; however, the reliance on self-reporting health presents an issue for the use of PROMs in some

contexts (Devlin & Appleby 2010). PROMs data should therefore be seen as complementing, rather than replacing, clinical and other information about patients.

Since 2009 in the UK NHS providers have been required to collect PROMs for four surgical procedures, including VV treatment; the other three procedures are hernia repair, and hip and knee replacements. Completion of PROMs is voluntary, and patients are under no obligation to take part. In 2013-14 PROM completion rates for VV patients was considerably lower than for the other procedures; just 40.5% compared with hip and knee surgery at nearly 86% and 94%, and an average of 76% across all four procedures (Health and Social Care Information Centre (HSCIC) 2016). There does not appear to be any established reason why VV PROM completion rates are so comparatively poor, however, one explanation could be that the PROMs being used do not contain items that are relevant to VV patients. The NHS currently uses the generic PROM the EQ5D/EQ5D-VAS (EuroQol 1990) and the condition specific Aberdeen VV Questionnaire (AVVQ) (Garratt et al 1993); to date there is no published evidence that the EQ5D has been validated for use with VV patients.

A recent systematic review (Aber *et al* 2017) was conducted to identify PROMs that have undergone some kind of published validation for use with VV patients, and assess their psychometric properties. Three disease-specific PROMs; the AVVQ (Garrett et al 1993), VV Symptom Questionnaire (VVSymQ) (Paty et al 2015), Specific QoL Outcome Response-Venous (SQOR-V) (Guex et al 2007), and one generic PROM, the Short-Form 36 (SF-36) (Ware et al 1992) were identified. The review concluded that based on its psychometric properties the AVVQ was the most appropriate disease specific instrument, with evidence of construct validity, test-retest reliability and responsiveness but less evidence for content validity and acceptability. An example of the questions from the AVVQ can be seen in appendix one. The SF-36 was the most suitable generic PROM, for use with patients with VV with satisfactory responsiveness and acceptability, but with limited assessment of other psychometric properties.

Currently NICE VV guidance suggests that 'Quality-of-life measures are unlikely to reflect severity of disease because of variations in perception of symptoms' (NICE 2013); therefore, it is necessary to assess whether these existing PROMs actually reflect the symptoms and issues that are most relevant to patients.

Content validity of PROMs is the extent to which items on a test are representative of what is intended to be measured. Content validity when developing PROMs can be enhanced by using qualitative research methods, such as interviews with patients, to determine which issues are

relevant to the patient group, and using these findings to develop the items incorporated into the PROM.

Whether used in clinical practice, or as a research tool, PROMs should be rigorously developed to ensure that they adequately represent, and capture, the experiences of the population they are to be used with.

QoL is central to the individual patient's experience of health and disease; measures of QoL must do more than describe a patient's health in terms of what health professionals and society believe constitutes health (Carr et al 2001). The measurement of improvements, or otherwise, in QoL associated with patient centred care should preferably be performed using PROMs that have been constructed with the involvement of those experiencing the health state.

This qualitative evidence synthesis is related to the identification and evaluation of existing condition specific or generic PROMs that have been validated for use in populations with vascular conditions. The synthesis is also an integral part of the development of a new PROM, specifically an electronic patient questionnaire (ePAQ-VAS) for use in this population. The review complements a series of other projects undertaken as part of a National Institute for Health Research (NIHR) Programme Grant – The Vascular Programme Grant (VPG) Project ID: RP-PG-1210-12009) (Michaels *et al* 2014) which has the aim of evaluating vascular services and making recommendations regarding patient-focused care. Programme work-streams include:

- Similar reviews of qualitative evidence of four other vascular conditions, (abdominal aortic aneurysm (AAA), carotid artery disease (CAD), peripheral arterial disease (PAD) and venous leg ulcers (VLU))
- Five systematic reviews identifying and evaluating PROMs used by patients with five vascular conditions (AAA, CAD, PAD, VLU and VV)
- Primary qualitative research into the experience of living with these five vascular conditions.

Aims

1. The primary aim of this qualitative evidence synthesis was to examine the symptoms and QoL domains that are important from the perspective of patients with varicose veins.
2. A secondary aim was to compare the themes identified in the synthesis to items in PROMs currently used with VV patients.

METHODS

This systematic review was conducted using explicit, systematic methods to reduce the risk of bias and provide reliable findings in accordance with published guidelines (Higgins et al 2011); specifically, a thematic synthesis was conducted as this is a recognised method used in systematic reviews of qualitative research which preserves an explicit and transparent link between review conclusions and the primary research (Thomas et al 2008). This review follows the design established in a pre-published protocol (Duncan *et al* 2016) titled; 'Understanding the experience and impact of living with a vascular condition from the patients' perspective'; and is reported according to the 'Enhancing Transparency in Reporting the Synthesis of Qualitative Research' (ENTREQ) statement (Tong *et al* 2012). The ENTREQ checklist can be seen in the supplementary file 1.

Study Identification and Selection

Studies were included if they were primary, qualitative research studies including populations of adults with VV, and published in English. Mixed-methods studies, where details of data collection, analyses and results of the qualitative portion of the study were reported separately, were included. Appendix two shows the eligibility criteria.

Searches were conducted in Cinahl, Embase, Medline, PsycINFO, Science Citation Index and the Social Science Citation Index, and ProQuest dissertations and theses. No language or date restrictions were applied as an initial scoping search had identified a lack of available literature in this subject area. Additionally, reference lists of included studies and related reviews were scrutinised, and citation searches were conducted (see appendix three for full details of the search strategy).

Two reviewers (EL, PP) independently screened the title and abstract of all studies identified by the searches, with reference to the inclusion and exclusion criteria in the published protocol. All potential full text papers were read, and discussion was used to resolve any difference of opinion. A third researcher (AA) was available for consultation if consensus could not be reached.

Data Extraction and Quality Assessment

Data extraction was conducted using a study specific data extraction form, details of author; date; country; research design; method of analysis; aims and objectives; sample, including age and gender;

diagnosis and eligibility criteria were collected (appendix four). The Critical Appraisal Skills Programme (CASP) qualitative research checklist was employed to assess the methodological quality of the included papers, including trustworthiness and relevance (CASP 1998). The CASP checklist was chosen as it assesses both the appropriateness and quality of reporting, and is commonly used in qualitative reviews of evidence (Carroll & Booth 2014). The checklist comprises of ten questions about the qualitative methodology and are answered either 'yes', 'no' or 'unclear'. Quality assessment was conducted independently by two researchers (EL, PP) and any discrepancies were resolved through discussion following the CASP criteria.

Data Analysis

Each full text paper was uploaded electronically into NVIVO 10 (QSR International, Burlington, USA), the reviewers read through each of the papers to familiarise themselves with the study and results, the results sections were then analysed using thematic synthesis (Thomas & Harden 2008).

Inter-observer agreement of coding was checked and consensus was high; showing substantial, almost perfect or perfect agreement with kappa coefficient rating commonly between 0.61-1 (Viera & Garrett 2005).

A provisional thematic framework (appendix five) was developed using conceptual domains from PROMs validated for use with VV patients (appendix six), that were identified in a separate review (Aber *et al* 2017).

Initial coding of the text was conducted independently line-by-line with relevant sections and quotations highlighted and assigned to the specific nodes of the provisional thematic framework. There was the potential to constrain or limit the deduction of new themes by using a preliminary framework however, it did not pre-determine the final themes.

Comparisons were made across the three included studies matching emergent themes to those already established in the framework. Where new concepts were identified additional themes were created and previously coded papers were re-visited to establish if any aspects of their findings matched the newly created theme. The classification of text according to existing and emergent themes is comparable to the development of descriptive themes in thematic analysis (Thomas & Harden 2008) where themes remain 'close to the primary study'. Figure one demonstrates the synthesis process.

Results

A total of 1804 references were identified, following the removal of duplicates 1318 citations were screened, of these 56 full text articles were retrieved and screened for eligibility of these 53 were excluded. Reasons for exclusion were: the paper was not available in English, the study population was not clearly defined solely as VV, or the study was not qualitative research, or did not detail data collection or analysis methods. Study selection is detailed in the PRISMA Flow Diagram (Figure two)

Three independent studies that met the inclusion criteria were identified (table one). The studies were published between 2004 and 2016 and were conducted in Sweden (n=1), and the UK (n=2).

Quality Assessment

The overall quality of the included studies was high with positive responses for most items on the CASP checklist (appendix seven). Positive responses indicate that the paper has met the relevant CASP criteria for credibility and rigour. However, two of the three studies did not fully consider that the relationship between the researcher and study participants, therefore potentially introducing bias into the research process. Studies were not excluded or weighted based on quality.

THEMES

Five overarching themes were identified; physical impact of VV, psychological impact, social impact, adapting to VV and reasons for seeking treatment. Within these main themes further sub-themes were identified: symptoms, symptom management, physical function, worry/anxiety, appearance, social restrictions and relationships (table two).

Physical Impact

The physical impact of VV was evident across all three included papers, as were the sub-themes of symptoms, management of symptoms and physical function.

Symptoms

Descriptions of pain, heaviness and itching were common to participants in all three studies with swelling reported in only two papers. Cramps, tingling and numbness were also reported as troublesome symptoms (Franz & Wann-Hansson 2015), reflecting the broad range of physical symptoms described across the three papers. The symptoms often had an impact on other aspects

of life, such as sleep, resulting in participants feeling tired. The distress associated with symptoms is clearly described by some study participants, whilst for others the symptoms were less troubling.

“They drive me mad, absolutely mad with the itching. I’ll scratch them and scratch them that much that I make them like, you know scratch marks, I make them bleed with the scratch marks.”

Participant 13 – Palfreyman *et al*

“It used to affect everything I would do, every day.....it was really awful....my legs were so sore and uncomfortable.” Patient 14 – Hudson *et al*

“They weren’t painful exactly, but erm at the end of the day I would be conscious of them, like they were achy, you know, not painful” Patient 9 – Hudson *et al*

Management of Symptoms

All three papers contained descriptions of how participants used different strategies to manage the impact of their symptoms. The main coping strategies employed were elevation of legs and the use of creams, ointments and compression hosiery. However, where these strategies were ineffective, or inappropriate, individuals called upon their own internal resources.

The use of compression hosiery was viewed differently in the two studies that comment; Franz and Wann Hansen, while acknowledging the difficulties involved in wearing compression hosiery, report benefits in reducing swelling and suggest, and that for some individuals, the use of stockings is crucial to getting everyday work done. In contrast Palfreyman *et al* report a widespread dissatisfaction with the use of compression hosiery by patients, which to some extent seemed to be shared by clinicians.

“The doctor (at the outpatient clinic) asked if I used stockings. I said they’re a waste of time. He says ‘You think so? I’m inclined to agree wi’ that’.” Participant 1 – Palfreyman *et al*

Palfreyman *et al* also noted the use of analgesia to manage pain and discomfort, with one participant describing the use of a range of non-steroidal anti-inflammatories (NSAIDs) with varying effects and another participant using paracetamol/ codeine combinations.

The management of symptoms theme is directly linked to the ‘Adapting to VV’ theme as all three papers report how participants make life adaptations, as well as practical ones to relieve symptoms, in an effort to cope with a life with VV.

“The last few days I literally crawled through the door and had to sit down with my feet up high to get the blood and swelling down.” Patient 14 – Hudson et al

“I put cream on, you know soothing cream like calamine and stuff like that and that voltarol gel, that’s quite good.” Participant 5 –Palfreyman et al

“I feel that the leg becomes a little more swollen when I don’t have the stockings on, especially down here where the socks end it may be more pronounced if I don’t have the compression stockings on.”

Informant 4 – Franz and Wann-Hansson

“So I tried them up to knee, like pop socks, and when you had them on for a bit, well they give you some right pain, you know where the veins swell? When you’ve had ‘em on a bit, they’re so tight stockings, your glad to get home and get ‘em off.” Participant 1 – Palfreyman et al

Physical Function

None of the papers identified that VV prevented specific activities of daily living such as personal care or housework; however, they clearly showed that participants experienced limitations in their daily lives, for instance being able to participate in leisure activities, walking distances or exercise. These restrictions sometimes resulted from physical problems when undertaking certain activities, however, some individuals whilst physically able, placed limitations on their activities due to the appearance of the VV; this demonstrates a close cross-over between the physical and psychological themes. The consequences of the physical impact of VV were best described as ‘not being able to live life fully’ (Franz and Wann-Hansson).

Two papers (Palfreyman *et al*, Franz and Wann-Hansson) identified that VV could affect the work lives of participants; both due to physical and psychological factors. Franz and Wann-Hansson found both those that were still working, and those that were now retired, spoke of the struggle of coping with symptoms and trying to find relief at work.

“I found that they (my legs) get very tired and heavy if I am on my feet for too long, or I have to walk too far, so it was always at the back of my mind, that my legs were too sore if I did too much.....”

Patient 20 – Hudson *et al*

Psychological Impact

Psychological impact encompassed sub-themes of worry or anxiety and appearance.

Worry or Anxiety

In all studies participants expressed worries about deterioration of VV, and the risk of future problems such as venous leg ulcers (VLU) or deep vein thrombosis (DVT). This anxiety was sometimes rooted in experiences of family or friends.

“Well, then the thoughts came that it could be something like that (ulcers) which is starting”

Informant 4 – Franz and Wann-Hansson

“I noticed a scratch and I was very worried about opening some skin or something, you know, and possibly getting an ulcer.” Patient 10 – Hudson *et al*

‘There was also a feeling amongst the participants that if they had surgical treatment it would prevent any further deterioration....’ Authors – Palfreyman *et al*

Appearance

The psychological effect of VV was also related to appearance; this was reported in all three papers and included personal feelings of embarrassment, disgust and feeling self-conscious. There was also the impact of the reactions of others, or the worry about a potential negative reaction.

“I was just very aware that my legs shouldn’t be like this and that if they were more normal and less ugly and swollen, then I would feel a bit happier.” Patient 2 – Hudson *et al*

“...because I don’t like being stared at and laughed at for something that I can’t particularly help. And they’ve upset me many a time when I was younger. They called me a freak and things for having them. And a lot of people would stare at them and make noises at me”.

Participant 11 – Palfreyman *et al*

“It’s more psychological that I think people are staring at my knees”

Informant 12 – Franz and Wann-Hansson

Accepted Article

These issues contributed to negative self-image and self-esteem for participants, both male and female. Again there is a link to the theme of adaptation, as the cosmetic impact of VV led to people adapting clothing to ensure they covered their VV; in addition they also altered the activities they took part in, such as sports and swimming.

“I was very conscious of them and wouldn’t wear shorts or skirts for a long time....I guess they weren’t that obvious to other people, but to me they were disgusting and I just felt more comfortable in trousers...or at least thick tights.” Patient 2 – Hudson *et al*

“You do not want to walk among people....and show your legs”

Informant 3 – Franz and Wann-Hansson

Palfreyman reported employment was affected for a female participant due to her concerns about the appearance of her VV and associated clothing restrictions.

‘She felt that any job that did not allow her to wear trousers meant that she would be unable to take up any job offer.’ Authors – Palfreyman *et al*

Social Impact

Impact on social functioning consisted of the sub-themes of restrictions and relationships.

Restrictions

All papers highlighted that participants had faced restrictions in their social lives. For some this had led to a degree of social isolation due to being unable, or unwilling, to participate in leisure activities or exercise.

“But everyone I meet says, ‘Can you come and exercise with us? It’s more fun when we are more people.’ But I can’t. I’ve tried twice. I have several friends who exercise twice a week.”

Informant 2 – Franz and Wann-Hansson

‘If any activity meant that they (participants) would have to expose their legs to public view they would cease to be involved.’ Authors – Palfreyman *et al*

The social impact of VV is further illustrated by Hudson *et al*, who describe study participants reporting the positive effects of surgery in terms of the removal of restrictions, allowing full engagement once more with life and others around them.

Relationships

There was also discussion of the impact on relationships. All papers reported that the negative emotions participants had experienced due to the appearance of their VV directly influenced how they perceived and interacted with others, both within a wider social context; Hudson et al also noted an impact on close personal relationships.

‘One participant reported that her symptoms influenced her interactions with her husband, leading to tensions in their relationship.’ Authors – Hudson et al

“I don’t feel comfortable I feel like a lot of people stare at them or feel repulsed by them.”

Participant 11 – Palfreyman et al

Reasons for Seeking Treatment

This theme was common to two papers (Palfreyman et al, Hudson et al), however it should be noted that exploration of reasons why people seek treatment was a specific objective of Palfreyman et al. Both papers identified that the primary reasons for seeking treatment were symptom relief, or to prevent worsening of their VV and the possibility of other complications. Expectations for the effectiveness of treatment were often found to be unrealistic (Palfreyman et al). Ameliorating the cosmetic appearance was a secondary consideration, despite the appearance of VVs being commonly reported across the papers as having a distressing psychological and social impact.

“More than anything is that it won’t be as it is now, so that the pain factor, the heaviness, everything that goes with it hopefully will have gone.” Participant 14 – Palfreyman et al

“One of my friends’ mothers had a lot of problems with her veins, I think she had an ulcer and I remember all the trouble that caused. I didn’t want something like that happened to me, so that spurred me on to get treated.” Patient 12 – Hudson et al

Adaptation

Adaptation was a common theme across all papers, with many different kinds of adaptations described. It is important to note that the coping strategies employed to manage symptoms that were previously discussed, should be differentiated from the life adaptations considered at this point. Franz and Wann-Hansson identified that the two concepts, though outwardly different were also intertwined;

'Strategies for relief were not only instrumental measures, such as the use of compression stockings, ointments, elevation of the leg and proper shoes....but also were inherent in the power of thoughts, as was described in learning to live with discomfort and acceptance of the disease.'

Authors – Franz and Wann-Hansson

Overwhelmingly these were life adaptations such as changing activities due to the impact on physical function, or coping strategies to deal with symptoms, and adapting work situations.

"Well, I have been thinking about the work situation...if it is possible to perhaps change the length of the period and the length of working hours during the day..."

Informant 9 – Franz and Wann-Hansson

'When it came to interests involving physical activity and exercise, the informants tried to find alternative activities that they could do despite their leg problems.'

Authors – Franz and Wann-Hansson

Adaptation also appears in relation to the theme of psychological impact, as in all papers there was mention of participants adapting what clothing they wore to disguise the appearance of having VV and the subsequent negative emotions this caused.

'Many participants reported shame regarding their legs and took measures to avoid exposing them in public, often at cost to their comfort.'

Authors – Hudson et al

'Those who had been living with VV symptoms for a long time had different methods to conceal their unattractive legs. For example, covering the legs with long pants or a sarong in the summer was one way of hiding them.'

Authors – Franz and Wann-Hansson

'In addition to the impact on their activities, the cosmetic appearance of their legs also influenced the type of clothing worn by participants.'

Authors – Palfreyman et al

DISCUSSION AND SYNTHESIS OF EMERGENT THEMES

The findings of the review have been discussed with reference to the domains used in PROMs that have undergone some form of published validation in populations with VV. This approach was taken

as PROMs are regularly used to assess the impact of VV on patients, to measure treatment results, and to support clinical decision-making.

The final thematic framework was closely related to the initial framework which emerged from analysis and synthesis of PROMs used and validated with a VV population (Aber *et al* 2017); this may lead to suggestions that a deductive, rather than inductive, approach was used. However, themes, such as adaptation, did emerge as a result of the analysis and syntheses, which are novel and to date not widely described in the existing literature, reflecting the inductive nature of the analysis.

In our synthesis we identify physical, psychological and social impact, in addition to reasons for seeking treatment, and adaptations, as the five key themes that should be addressed in the design of future PROMs, and in the provision of care to patients with VV. Table three demonstrates which PROMs validated for use with VV patients have domains or items that correspond with the themes identified in this review; it should be noted that the VVSymQ was developed solely as a symptom report questionnaire.

The range of physical symptoms reported across the three papers was varied, for example swelling is not mentioned by Palfreyman yet appears strongly in the other two included papers; in addition, swelling is also a domain in all of the VV specific PROMs (AVVQ, VVSymQ and SQOR-V).

The degree to which people were bothered by symptoms of VV, such as pain, also varied widely both within and across the papers. For some the symptoms appeared to make the participants 'aware' of their VV, whilst for others the pain could be debilitating, resulting in restrictions in their lives and requiring the need for active management.

The diversity and impact of the symptoms reported across the three papers demonstrated that there is no definitive list of VV symptoms, and that not all symptoms affect everyone in the same way.

The subjective nature of symptom experience has implications for the use of PROMs, as specific symptoms may not be included in the PROM, for example worries about the appearance of VV; or there may be symptoms, such as itching, that are included but that are not typical to all patients. There are also implications for clinical decision-making due to the difficulty in measuring symptoms of VV, as NICE (2013) guidance for the management of VV states 'QoL measures are unlikely to reflect severity of disease because of variations in perception of symptoms'.

The variety of descriptions of practical day-to-day symptom management across the papers highlighted the variety of methods that VV patients employed. This may demonstrate a deficit of

information available to patients about the most effective means of symptom control, and the importance of adherence to recommended management options.

This review also found inconsistency in the use of compression hosiery, as the two papers that covered it offered contradictory points. The participants in Franz and Wann-Hansson appeared to have more positive experiences of the use of compression than those of Pafreyman. What is not clear is whether this differentiation could be due to poor adherence, lack of understanding of the benefits of compression, or using incorrectly fitted compression hosiery.

The sub-theme of physical function related more to physical limitations rather than an absolute inability to carry out physical tasks. The lack of clear physical impact may be a contributing factor in the reluctance of some NHS trusts in the UK to fund VV surgery, if the assumption is that lack of measurable restriction does not merit costly, and not necessarily fully effective, intervention.

Recurrence of VV after conventional surgical treatment is a common, costly, and complex problem, which accounts for over 20% of patients requiring venous surgery (Groenendael et al 2009). Gad *et al* (2012) noted reoccurrence rates of 60% after 5 years; injection sclerotherapy was suggested to have a higher than 20% reoccurrence rate (Sheffield Teaching Hospitals 2011).

The generic PROMs used in the VV population, and the specific instrument AVVQ, both have 'physical function' domains; however, based on the findings reported in the included studies a PROM domain related more to 'physical limitations', such as that in the SF-36, is perhaps more applicable. The SQOR-V includes questions asking to what extent VV affects activities such as standing, sitting, walking and using the stairs; this emphasis on extent of limitation rather than prevention of carrying out an activity is perhaps more relevant.

The psychological impact of living with VV appears strongly in this review, with all three papers demonstrating a significant impact. Fears of further deterioration and future problems, such as developing VLU or DVT, were common in many patients across all papers; this common anxiety has been described as an 'exaggerated sense of risk from VV' by NICE (2013). There appears to be little reliable evidence about the proportion of VV that progress to VLU with perhaps only an estimated 3-6% of people with VV affected (Nelzen 2008). Ensuring patients are well informed about their VV condition, and about the risk of other complications, may go some way to mitigating unnecessary worry and anxiety.

Only one VV specific PROM, the SQOR-V, includes domains that would enable patients to report psychological, emotional or mental impacts, relevant to the anxiety and worry reported in this review. The SF-36 also includes domains that capture both emotional and mental health.

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The significance of the cosmetic appearance of VV has perhaps historically been trivialised in comparison to the impact of symptoms; however, this review found that appearance was a significant psychological issue for patients. All three papers highlighted feelings of distress and embarrassment felt by patients due to the look of their VV. This was both due to their personal perception and the reactions of others.

In the NICE vascular referral guidelines 'body-image concerns' is included as an important measurable outcome of patient-assessed symptoms, and 'appearance' is included as a domain in the AVVQ and the SQOR-V; however, it would not be specifically captured by either the VVSymQ or generic PROMs.

Social function was clearly found to be affected in all papers, often leading to varying degrees of social isolation. The impact of some VV symptoms resulted in some participants being unable to undertake usual leisure activities and hobbies. For others it was down to avoidance due to a reluctance to expose their VV.

In both cases the outcome of social isolation prevented people from living their lives fully, and often had implication for personal relationships with partners, friends and family. It would appear that there is potentially a close link between social and psychological impact, with social isolation contributing to feelings of low mood. Impact of VV on social activities is measured by the SF-36, the SQOR-V and the AVVQ.

Symptom relief rather than the cosmetic appearance was the primary reason for seeking treatment in the two papers that explored this theme.

Existing literature demonstrates that improvement in symptoms is a common, yet potentially unrealistic, expectation. Dillon *et al* (2005) reported that 75% of participants expected VV treatment to improve their symptoms, whilst Darvall *et al* (2009) found that 100% of their participants had expected some improvement following treatment yet 20% had unmet expectations.

If patients feel that their treatment has not met their expectations this is likely to have an impact on their QoL. Healthcare professionals need to ensure that all patients are fully informed about potential benefits and risks of treatment, including the fact that they might need more than one treatment, they may have a reoccurrence, and they may develop new VV in the future.

Current PROMs do not include a clear process for patients to highlight their reasons for seeking treatment, therefore healthcare professionals may find themselves unable to judge whether or not patients have realistic treatment expectations.

Participants adopted a wide range of adaptations in order to enable them to continue to live their lives as fully as possible. This was notable in all aspects pertaining to the impact of VV on QoL, physically, psychologically and socially.

Some adaptations may be characterised as passive, for instance when an individual stops doing something because of pain or appearance; whereas other adaptations may be regarded as positive – rather than stopping exercise because of appearance or discomfort a new form of exercise is adopted.

The ability of VV patients to positively adapt to their condition and make the adjustments necessary to continue working, and otherwise safeguard their health and wellbeing, is one suggested reason for the perception of VV as a cosmetic condition (Franz & Wann-Hansson 2015).

An expectation of successful treatment for patients may be that they would no longer have a need to adopt these adaptations, thus leading to a resumption of 'normal' life.

No available PROM, validated for VV populations, currently exists that would fully capture how patients adapt their lives to their condition. The AVVQ and the SQOR-V both ask if clothing choice is affected by VV, and the SQOR-V asks if choice of activities is influenced by VV; however, this does not fully cover how patients 'adapt' or employ 'coping strategies' to live their lives fully.

Further Research - Construction of PROMs

The content validity of a PROM can be determined by examining the relevance to patients of the items included. This can be assessed by considering whether or not items were developed through qualitative studies with patients and incorporating qualitative evidence from the literature.

Accepted guidance suggests that PROMs should be developed using patient generated information (FDA 2009). This information is best generated using qualitative research methods, either through conducting a primary qualitative study or systematic reviews of existing qualitative literature; both of these methods offer greater insight into patient experiences.

Of the three condition-specific PROMs identified in this paper only one, the VVSymQ, incorporated qualitative patient based findings into development. The AVVQ items were based on common clinical assessment questions of VV patients, and the SQOR-V used a committee of 'experts' to review existing questionnaires and analyse relevant literature.

An identified aim of the developers of the SQOR-V was in fact to develop a questionnaire that considered the patients' main concerns yet it appears that they did not consult patients about the construction of items. They also concluded that 'content validity could be inferred as questions were created for clarity and completeness by a group of experts in the field' (Guex *et al* 2007); it hard to understand how anyone could have more insight than the person who lives with the condition.

Familiarity with the findings of existing qualitative literature through qualitative reviews, or employment of qualitative research methods such as interviews, enables an in-depth understanding of the range and severity of symptoms, and resulting impact on QoL, experienced by patients.

Qualitative methods should be used in the development of PROMs to ensure that they reflect the most relevant issues patients face, therefore enhancing the content validity of such measures.

The findings from this review have been utilized in the development of a new electronic PROM (e-PAQ-VAS), which is intended to be used with patients with a range of vascular conditions. It complements similar reviews that have been conducted with patients who have abdominal aortic aneurysms, peripheral arterial disease, carotid arterial disease and venous leg ulcers; and the findings from a primary qualitative research study.

Conclusion

Health-related quality of life, patient-assessed symptoms (including pain, discomfort, body image concerns, swelling, aching, and heaviness), and progression have been cited as the most important outcomes to identify which people would benefit from a referral to a vascular service (NICE 2013).

The use of PROMs to gather such information is well established however, as this review has shown, those PROMs currently validated for use with patients with VV, both generic and condition-specific, may not capture the full extent of the impact of VV on patient's QoL.

Healthcare professionals involved in the assessment and care of patients with VV, and those involved in planning vascular service provision, need to be as familiar as possible with the lived experience of such individuals in order to provide a patient-centred service.

Relevance to Clinical Practice

- ❖ PROMs data is collected pre and post VV surgery so healthcare professionals should be familiar with the instruments used, and have awareness that the questions contained within these instruments may not accurately reflect patients' experiences of living with VV. As VV have a diverse range of symptoms, and the impact can be wide reaching on many different aspects of QoL; this can be difficult to capture.
- ❖ The various adaptations patients employ in order to cope with their VV may mask the full impact of their condition.
- ❖ Healthcare professionals have a responsibility to ensure patients are aware of both the most effective means of symptom control, and the importance of adherence to recommended management options. Healthcare professionals should also be properly trained in the fitting of compression hosiery in order for patients to potentially receive benefit from them.
- ❖ Patients with VV may have unfounded fears of future problems such as developing VLU or DVT; healthcare professionals should ensure patients are well informed about their condition, and the risk of other complications, in order to mitigate unnecessary worry and anxiety.
- ❖ Healthcare professionals need to ensure that all patients have realistic treatment expectations, including potential risks of treatment, such as the fact that they might need more than one treatment, they may have a reoccurrence, and they may develop new VV in the future.

Limitations

This paper is subject to limitations both due to the age of one of the included studies, and to the small number of studies included overall. Inclusion of a paper 14 years old may limit the relevance of its results, and therefore the findings of this review. Only 3 studies were included in this review potentially affecting the representativeness of the thematic findings, and therefore the conclusions reached in this paper. As with primary qualitative research, where relatively small samples are the norm but selective sampling can continue until data saturation has been achieved, qualitative evidence syntheses can benefit from inclusion of and access to, multiple studies so that the experience of living with VV can be understood in different contexts and circumstances. The lack of available qualitative literature on this subject could suggest that this condition is often overlooked, and that the subject would benefit from further in-depth qualitative research.

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Table One. Included Studies

Author and Year	Country	Research Design	Sample	Main Findings
Franz and Wann-Hansson (2015)	Sweden	Exploratory qualitative study with phenomenological approach Phenomenological Reduction	12 (Purposive sample) Age 56 (mean) (range 32-72) Gender (42%male) (5/12)	The essence meant adapting to a life with VV, relieving discomfort from legs with an unfavourable appearance. Coping with discomfort involved dealing with the disease emotionally and finding strategies that helped to relieve symptoms; however, living with 'repulsive' legs was seen as embarrassing, and many found the need to hide their condition.
Hudson et al (2015)	UK	Qualitative semi-structured interviews (qualitative section of a mixed-methods study including an RCT) Thematic Analysis	20 (4 from each arm of the wider RCT) Age (mean) 50.8 years Gender (30%male) (6/20)	Four themes captured (1) Negative emotions associated with symptoms (2) Unpreparedness for the surgical process (3) Feeling cared for (4) Improvements in well-being. An overarching theme of relationships was identified. VV had a detrimental impact on QoL prior to surgery; post-surgery QoL improved.
Palfreyman et al (2004)	UK	Qualitative using semi-structured interviews. Framework Analysis	16 (purposive sample) Age (mean) 51 years (range 20-75) Gender (19%male) (3/16)	Participants attributed a wide range of symptoms to their VV, and were actively seeking treatment with the expectation that they would gain symptom relief. The symptoms attributed to VV had a significant negative impact on QoL and lifestyle. Improving the cosmetic appearance of their legs was seen as a secondary benefit.

Table Two: Themes identified from included papers

Main Theme	Sub-Theme	Palfreyman et al 2004	Hudson et al 2015	Franz & Wann-Hansson 2015
1. Physical Impact	Symptoms	✓	✓	✓
	Heaviness	✓	✓	✓
	Itching	✓	✓	✓
	Pain	✓	✓	✓
	Swelling	X	✓	✓
	Other Symptoms (phlebitis, tiredness)	✓	✓	✓
	Sleep	✓	X	✓
	Management of symptoms	✓	✓	✓
	Coping Strategies	✓	✓	✓
	Compression	✓	X	✓
	Analgesia	✓	X	X
	Elevation	✓	✓	✓
	Physical Function	✓	✓	✓
	Limitations	✓	✓	✓
	Work	✓	X	✓
2. Psychological Impact	Worry/Anxiety	✓	✓	✓
	Future Health Problems	✓	✓	✓
	Deterioration	✓	✓	✓
	Appearance	✓	✓	✓
	Personal Feelings (embarrassment, self-conscious, disgust)	✓	✓	✓
	Reactions of Others	✓	✓	✓
	Self-Image/Self-esteem	X	✓	X
3. Impact on Social Functioning	Restrictions	✓	✓	✓
	Relationships	✓	✓	✓
4. Reasons for Seeking Treatment	Symptom Relief	✓	✓	X
	Cosmetic Concerns	✓	✓	X
	Prevent Future Problems	✓	✓	X
5. Adapting to VV	Life Adaptations	✓	✓	✓
	Clothing Adaptations	✓	✓	✓

Table Three – PROMs items and corresponding qualitative review themes.

Qualitative Review Analysis Themes	PROM				PROM Item or domain ^{PROM origin}
	SF-36 ¹	AVVQ ²	SQOR-V ³	VSymQ ⁴	
Physical Impact Adaptation	✓	✓	✓	X	Physical Function ¹ Physical Limitations ¹ Physical Function/Activities ² Restriction of Movement ³
Social Impact Adaptation	✓	✓	✓	X	Social Activities ¹ Leisure/Social Activities ² Restriction of Activities ³ -including social /sport or leisure/activity choice
Psychological Impact Adaptation	✓	X	✓	X	Mental Health ¹ Emotional Health ¹ Emotional Distress ³ – including worry/worsening/complications
Physical Impact Adaptation	✓	✓	✓	✓	Pain ¹ Pain/Ache ² Pain/Discomfort ³ Aching ⁴
Psychological Impact	✓	X	✓	X	Health Perceptions ¹ Risk/Threat to Health ³
Psychological Impact Adaptation	X	✓	✓	X	Appearance ² – including clothing choice Appearance/Attractiveness ³ – including clothing choice
Physical Impact	X	X	✓	X	Progression ³
NA	✓	X	X	X	Vitality ¹
Physical Impact Adaptation	X	✓	✓	✓	Symptoms ^{2,3,4} – Swelling ^{2,3,4} Itching ^{2,3,4} Heaviness ^{3,4} Throbbing ⁴ Skin ² - Discolouration/Rash/Ulcer Sensation ³ – Warm/Burning/Tingling/Stinging/Stabbing Restless Legs ³ Night Cramps ³ Worse with heat/Improves with cold ³

Figure One: Application of framework synthesis:

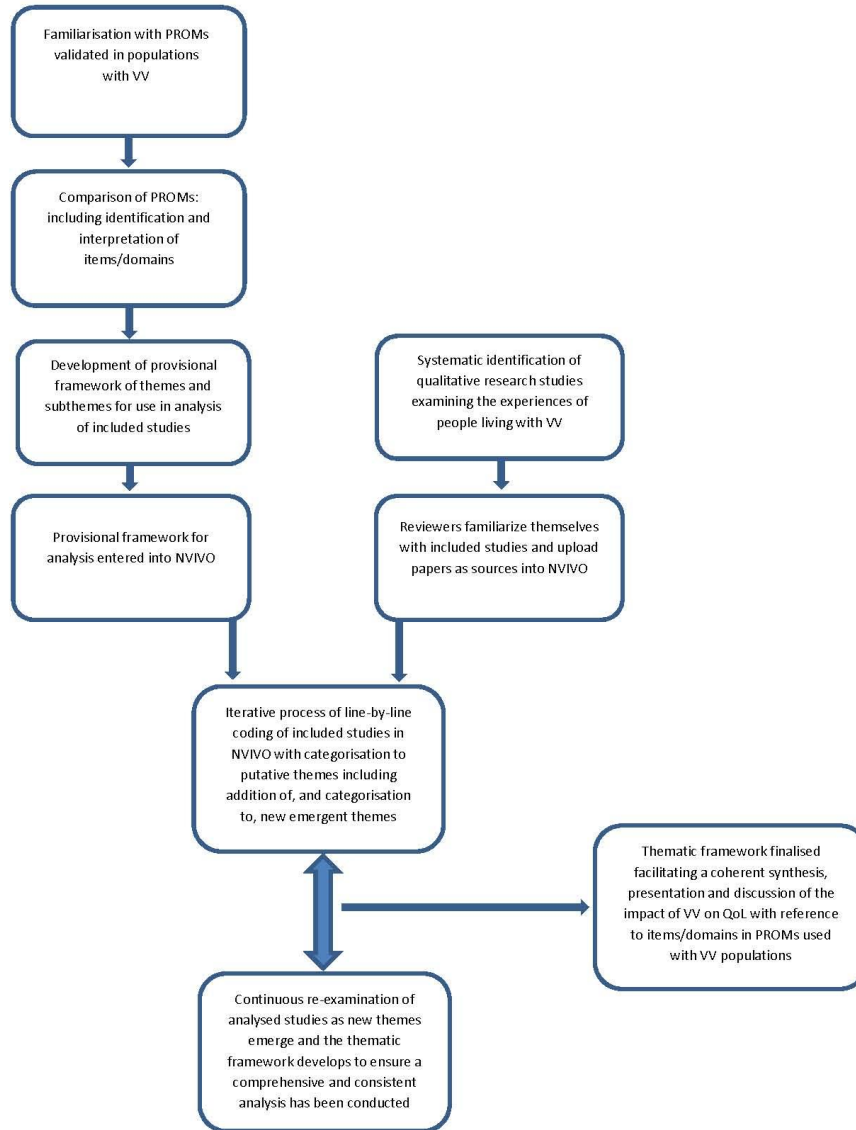
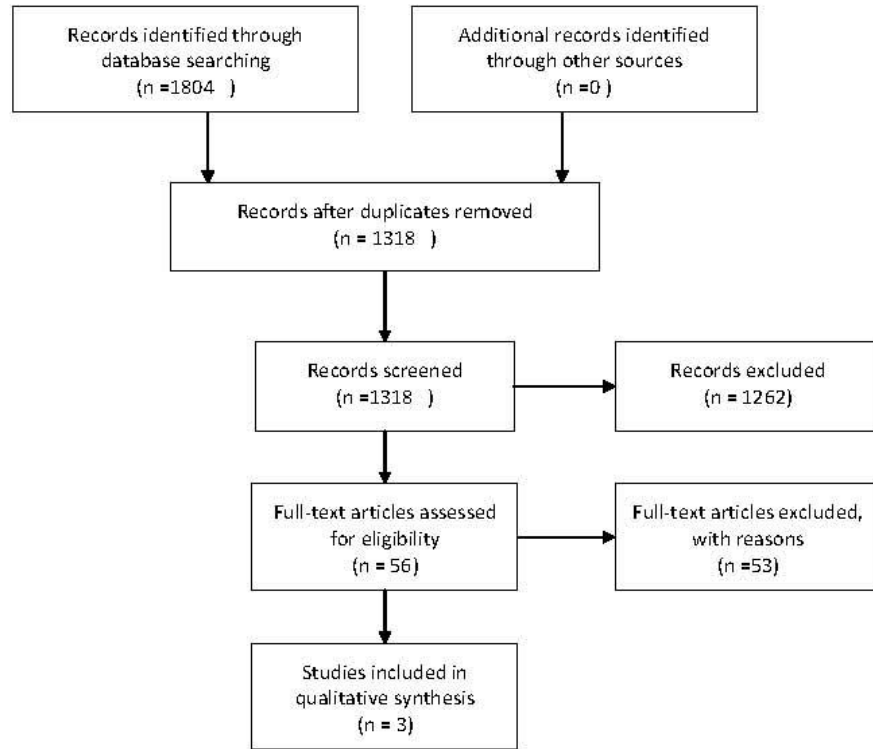




Figure 2. PRISMA 2009 Flow Diagram



From: Moher D, Liberati A, Tetzlaff J, Altman DG, The PRISMA Group (2009). Preferred Reporting Items for Systematic Reviews and Meta-Analyses: The PRISMA Statement. PLoS Med 6(7): e1000097. doi:10.1371/journal.pmed1000097

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