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Invited Review

Patient reported outcome measures (PROMS) and patient reported experience measures (PREMS): Measuring outcomes in pelvic venous disorders

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Abstract

Pelvic venous disorders (PeVD) present with a range of heterogenous symptoms that arise from altered venous hemodynamics in the pelvis. Many of these symptoms lead to mental health and quality of life issues and are not limited to the pelvic region. The nutcracker phenomenon causing left renal vein compression and left ovarian venous hypertension as well as the compression of the left common iliac vein by the overlying right common iliac artery are often stated as the common underlying pathologies. As a result, there has been a sudden increase in the number of ovarian vein coil embolizations and iliac vein stents placed. In truth however, the altered venous hemodynamics in PeVD is more complex. There appears to be little correlation between the symptoms patients experience and the obvious image detected anatomical lesions being treated. In addition, these anatomical lesions are very commonly seen in asymptomatic and especially muti-parous women as well. To compare outcomes of these and other more extensive procedures being performed for these commonly seen anatomical changes in the pelvic veins, objective assessments of the outcomes as seen from the symptom relief they bring to patients treated is essential. Validated Patient-reported outcome measures (PROMS) can be an important tool to compare outcomes across interventions for PeVD. However, as the impact of similar symptoms on different patients' quality of life (QoL) can vary, developing a validated PROM that can be used to compare procedural outcomes in PeVD is a challenge. On the other hand, complications and procedural success as reported by physician do not assess the effect on a patient's QoL. This paper provides a narrative review of PROMs, patient reported experience measures (PREMs) and individualized-PROMs. It also suggests a process for how a validated PROM for comparing procedural outcomes in PeVD may be developed. This could provide a framework that incorporates the recently adopted Symptoms-Varices-Pathophysiology (SVP) classification of pelvic venous disorders into the PROM development process to ensure that a like-for-like comparison is made between procedures being performed on a very heterogenous, but long-suffering group of patients.

Keywords: Pelvic venous disorders, patient reported outcomes, patient reported experience measures

INTRODUCTION

Pelvic venous disorders (PeVD) consist of a spectrum of symptoms of chronic pelvic pain and discomfort, dyspareunia, dysmenorrhoea and menorrhagia, groin and vulvar varices and symptoms of lower limb venous insufficiency [1]. Now classified under the Symptoms-Varices-Pathophysiology (SVP) classification [2], the condition is a functional disorder of venous hemodynamics in the pelvic veins and in the interconnected veins in the lower limb that can affect up to 6-27% of women world-wide [3].

Many of these women are multiparous, and the anatomical changes like left renal vein compression at the aorto-mesenteric angle, left iliac vein compression by an overlying right common iliac artery, dilatation of the ovarian and adnexal veins that are the underlying pathophysiology of the condition are often seen in many asymptomatic women as well. The symptoms overlap with

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other gynaecological pathology also commonly seen, especially endometriosis [4]. In addition, no single symptom or group of symptoms defines the underlying disorder. A combination of pelvic symptoms, difficult to quantify symptoms like fatigue, dizziness, palpitations and temperature intolerance that occur with the associated POTS (paroxysmal orthostatic tachycardia syndrome) [5], as well as the psychological impact of dyspareunia, heavy menses, and the consequent strain on the personal life of patients makes measurement of treatment outcomes very difficult indeed. This is especially relevant when symptom control and anatomical or radiological imaging changes post-intervention do not correlate with each other.

Recent years have seen an enhanced understanding of the condition, as well as a sudden increase in the endovascular treatment options being offered and procedures performed [6]. This raises the possibility of inappropriate procedures being performed for imaging-detected anatomical findings like an iliac vein compression or a dilated ovarian vein without a hemodynamic abnormality being demonstrated.

PeVD is essentially a functional disorder with a range of symptoms that have a significant effect on the quality of life. Measurement of outcomes therefore must necessarily include objective assessments of symptom relief and quality of life. Such outcome measures cannot be limited to technical imaging or clinical observations like ovarian vein recanalization, iliac stent occlusion and the like, as symptom improvement and the return to a normal quality of life must be the true measure of treatment for a functional disorder. An added issue in PeVD is that the symptoms vary according to the SVP classification zone where the variceal reservoirs may be affected [2], and different women experience these symptoms very differently. The outcomes measured therefore must reflect the patient's own experience of the condition and the disease.

Patient-Reported Outcome Measures (PROMs)

Outcomes across a patient-health care provider interaction, as perceived and reported by patients, are being increasingly used to measure health care delivery and for comparing different providers – be they different clinicians or different institutions. PROMs are tools that measure patient-reported outcomes via a standardised validated questionnaire. These questionnaires measure the patient's assessment of their health-status, disability, symptom severity, degree of functional impairment and health related quality of life before and after procedures or operations [7]. The questionnaire thus measures the efficacy of a procedure from the patient's perspective.

PROMs may be generic or disease specific [8]. Generic PROMs measure many aspects across a broad range of medical conditions, and are useful in the overall assessment of care, quality of life and effectiveness of interventions. The EQ-5DTM and the SF-36 questionnaires are examples of generic PROMs. Disease-specific PROMs, on the other hand, focus on a specific condition and allow for the individual aspects of a condition and its impact on the outcomes to be examined – the Oxford Hip score and the Aberdeen varicose vein questionnaire are examples here [7].

These traditional generic and disease-specific PROMs have been criticized on the grounds that they do not capture the uniqueness of individuals. Instead, they measure the patient's perception of her health or quality of life (QoL) through the lens of a standardised model of 'good health/ good QoL' using pre-selected domains or weights. Measures like the Oxford Hip Score which were developed using classical psychometric methods cannot be used to pinpoint individual patients who have had good or bad outcomes. They can, however, be used to compare the outcomes of procedures at a group level.

This is especially relevant in pelvic venous disorders, where there is both a significant heterogeneity in the symptoms experienced by patients, as well as a wide variation in the impact these symptoms may have on the patient's quality of life. For instance, post-coital pain in a 30-year-old lady in a relationship with a partner actively seeking intimacy has a different QoL impact as compared to a 48-year-old lady married to a 55-year-old partner on anti-androgenic therapy for benign prostatic hyperplasia. Menorrhagia may have a greater QoL impact on her daily activities. When it comes to outcome measures in a functional disorder, one size does not fit all.

Individualised PROMs (i-PROMs)

Like traditional PROMs, i-PROMs are instruments (usually questionnaires) that measure health status and related concepts such as quality of life. However, unlike traditional generic or disease-specific PROMs, they allow each respondent to individually define the domains and weights to be assessed within the questionnaire, and hence are also called 'Patient Generated Outcome Measures'.

An example is the Patient Generated Index (PGI), which is an individualized PROM whose methodology can be adapted to develop i-PROMs for specific diseases like PeVD. The PGI questionnaire method asks respondents to nominate domains or aspects of life that are important to them, rate how they function in these areas, and give points to them according to how they would most like to see an improvement [9]. Patients are asked to list the five most important domains affected by their condition. Also given is a list of the symptom spectrum most frequently mentioned by patients with the same condition. A sixth domain represents all other aspects of life that are not captured in the first five areas. Patients rate how their current condition matches their expectations in each of the six areas of life using a scale of 0 to 10. The six domains are weighted by distributing 12 points, these weights are then converted to a 0-1 scale.

$$\text{PGI index} = \Sigma \text{ (levels x weights): ranges from 0-10.}$$

The Psychological Outcomes Profile (PSYCHLOPS) is another such validated i-PROM that has been used to measure the outcomes of psychotherapies in patients with eating disorders [10].

Patient-Reported Experience Measures (PREMs)

The concept of "the patient experience" has become an integral part of assessing health care systems and for directing quality improvement in recent years. With greater emphasis on patient-centred care comes the recognition that patients are best (or solely) qualified to provide information about what matters to them, and about how they perceive various elements of their interactions with healthcare providers; only the patient themselves can indicate if they felt treated with respect, or whether information was provided in a way they could understand. Patient experience data can vary from qualitative information collected through interviews or focus groups through to large quantitative datasets derived from standardised surveys.

PREMs are such a standardised survey tool to inform health care stakeholders of one important aspect of care provided within a centre or hospital or in a region. PREMs are survey tools used to record patient perceptions about various elements of the healthcare they received. They are distinct from satisfaction surveys, though PREM surveys will often include one or more items seeking an overall opinion about a patient's experience [11].

It is important to emphasise here that PREMs do not measure pathophysiological outcomes or complications before and after procedures. Rather, they are a measure of patient involvement and ownership in the care process. As such therefore, they cannot be used in PeVD for comparing the appropriateness or efficacy of a particular procedure. Nevertheless, they are an important tool to guide service delivery improvement particularly for front line staff dealing with pelvic venous disorders. Patients with PeVD often have suffered significant mental distress from many years of misdiagnosis or dismissal of their symptoms, and from a failure to have their symptoms and prognosis explained to them in an empathetic way, and PREMs are an objective way to assist clinics and hospitals providing PeVD treatment to constantly strive to improve the patient experience.

At the time of writing however, there were no validated PROMs, i-PROMs or PREMs for pelvic venous disorders.

Current Tools for the Assessment of Patients with a PeVD

Two different patient-reported tools to measure the impact of the disease state in a patient with PeVD currently exist, each with their potential uses and pitfalls.

The Venus PeVD score, developed by the author at The Venus Clinic, Singapore, is a patient-reported symptom questionnaire to screen patients with pelvic symptoms for suitability for further diagnostic assessment for PeVD [12] (presented at the International Union of Phlebology, 2023 and submitted for publication). Patients complete a 6-item questionnaire, resulting in a Basic Score and an additional 4-item questionnaire developed as an adjunct resulting in a Specific Score - adding Basic and Specific Scores yields the Combined Score. The score was validated against a trans-abdominal-trans vaginal Duplex ultrasound (DUS) examination in all women, with the DUS result indicating the presence of PeVD used as the reference standard to calculate the accuracy of the Basic and Combined Scores. The results suggest that a Basic score of ≥3 and a Combined score >5 have a high likelihood of abnormal DUS findings of PeVD. However, the diagnostic accuracy may be over-estimated due to the high disease prevalence in the cohort, and the authors state in their submission that the score questionnaire requires full validation within a primary-care population where it is intended to be used.

The Venus PeVD score therefore should not be used to as a diagnostic tool or to measure outcomes in PeVD – meaning that a decrease in the score from before to after a procedure should not be taken to mean efficacy of a procedure. This score is meant to screen and identify those patients with symptoms like those usually seen in PeVD for whom further evaluation for PeVD is appropriate.

The Pelvic Varicose Vein Questionnaire (PVVQ) is an original QOL questionnaire for patients with a PeVD [13]. Based on the CIVIQ-20 tool [14], it has been adapted to incorporate the symptoms often seen in PeVD. PVVQ reflects 4 main dimensions of a person's physical and mental health as may be affected by the condition: pain, physical and social activity, and psychological well-being. Each dimension includes 5 questions that are graded from 1-5, reflecting an increasing severity of the symptom.

The PVVQ was assessed statistically for reliability, validity and sensitivity by comparing the scores of 309 women with "verified PCS (pelvic congestion syndrome)" with 93 control patients without symptoms of chronic venous disease. Whilst the use of these domains is an encouraging first step as a possible PROM for PeVD, two issues arise. Firstly, the individual symptoms in each dimension or domain have themselves not been validated as being relevant to these patients by first developing the questionnaire with a patient population and then applying the most relevant questions to a second cohort for validation – a key step in PROM development [15]. Secondly, the method of "verifying PCS" is unclear in the publication. It is unlikely therefore to be suitable as a PROM that can be used for outcomes comparison in PeVD, although as a patient reported QoL measure, it's domains can help in the development of a future disease-specific PROM for PeVD.

A Suggested Approach to Developing a Prom for Comparison of Procedural Outcomes in PeVD

The Symptoms-Varices-Pathophysiology (SVP) classification, which is being rapidly adopted by clinicians treating PeVD, provides an excellent framework for developing a PROM that can be used for comparing outcomes of interventions for the condition.

Under the SVP system, the venous system relevant to PeVD is classified into 4 zones [2] – zone 1 includes the renal vein and the renal hilar veins, zone 2 includes the ovarian veins, adnexal or para-uterine veins, the uterine venous arcade and the common and internal iliac veins (anatomically above the pelvic floor), zone 3 includes the veins in the superficial perineal pouch (para-urethral, para-vaginal, para-rectal, pre-sacral, vulvar and labial veins- anatomically below the pelvic floor) and veins in the lower limb.

The symptoms that arise from these zones, namely flank pain and haematuria from zone 1; chronic pelvic pain, dysmenorrhoea, menorrhagia, deep coital pain and post coital pain from zone 2; pelvic and/or coital pain, perineal bleeding and discomfort and low back pain from zone 3; and leg heaviness, swelling and frank varicose veins from zone 4 – are all well recognised as possible PeVD symptoms, although this list is not comprehensive. The symptoms themselves are related to pressure, stasis and hemodynamic disturbance in the variceal reservoirs that lie in these zones. The pathophysiology may be one of reflux, anatomical or functional obstruction in one or more of these zones causing upstream rises in venous pressure and venous stasis in the relevant reservoir with consequent changes of chronic venous insufficiency in the pelvic and limb veins.

The treatment offered to a patient to relieve these symptoms of PeVD follows two basic principles:

1. Reduce or ablate the venous reservoir that is the source of these symptoms – which may be a large trans-uterine arcade causing menorrhagia or vulvar veins causing perineal pain, discomfort and bleeding. This may include image guided foam sclerotherapy or glue embolization of the relevant reservoir.

2. Stop or reduce significantly, the upstream transmission of pressure into that venous reservoir via coil embolization of ovarian or iliac veins, iliac or renal vein stenting, or open surgical procedures like renal vein re-implantation or gonadal vein transposition.

The choice of procedure therefore depends on the nature (occlusive or reflux) and anatomical location of the underlying pathophysiological lesions, and the venous reservoirs causing the specific symptoms. The PROM must of course, be an objective, and validated, patient-reported assessment of how well the interventional combinations offered (unilateral coil embolization with sclerotherapy, for example) have relieved their symptoms and returned their quality of life to what they perceive as normal.

A suggested approach must therefore incorporate both the disease-specific PROM and the i-PROM methodologies. The steps of such an approach could be as follows:

1. A questionnaire with an extensive list of PeVD-based symptoms is developed and administered to a cohort of female patients in the ages 21 to 50 years presenting to family physicians (general practice) for routine health assessments and symptoms unrelated to the pelvis or lower limbs.

2. The questionnaire is also administered to a separate cohort of patients of the same age-group, who present with the key symptoms of flank pain, chronic pelvic pain, dyspareunia (coital or post coital), menorrhagia and venous insufficiency (varicose veins, leg heaviness and swelling) to gynaecology, urology, cardiology (if under assessment for POTS), vein and vascular clinics and primary care physicians. The question for each symptom would be "how much would having this symptom affect your daily life", with simple responses of "severely, moderately, slightly, or not at all". This is an essential step to assess if patients with possible PeVD perceive the impact of these symptoms differently from those who are unlikely to have PeVD.

3. Should there be no heterogeneity between these groups, the questionnaire is then modified by removing the questions that generate "slightly or not at all" responses in over 95% (statistically 2 standard deviations from the mean) of the respondents. These can be categorised into the domains of pain, effect on physical activity, social activity and psychological well-being as in the PVVQ questionnaire and validated in a new cohort of patients with PeVD confirmed by cross-sectional imaging as per usual the PROM development methods.

4. If there is heterogeneity between the two groups, then an i-PROM method as in the Patient Generated index, with additional weightage as needed for the symptoms where heterogeneity is detected, may be used to develop a PROM specific for PeVD patients, and validated in a new cohort of patients with imaging-confirmed PeVD.

Once a validated PROM or i-PROM for PeVD is developed, its use as a comparative outcome measure must only be done between patients of similar SVP grade. In other words when two procedures for PeVD are compared using the validated PROM score as an outcome measure, this should be done for groups with similar PeVD hemodynamics as classified by the SVP grade. The PROM scores for different domains would understandably be different for patients with primary zone 3 disease compared to those with zone 1 disease. The development of a disease-specific PROM for PeVD based on the process outlined above is currently underway at The Venus Clinic, Singapore.

CONCLUSIONS

Finally, Physician-reported outcomes like coil migration, stent stenosis, thrombosis or migration, venous thromboembolic episodes and procedural complications like access site hematomas and non-target embolization or sclerotherapy must also be reported when comparing PeVD procedures. Whilst these are not patient reported outcomes, these have the potential to cause significant co-morbidity and affect the patient's quality of life.

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