Capturing venous thromboembolism: imaging and outcomes of venous thromboembolism

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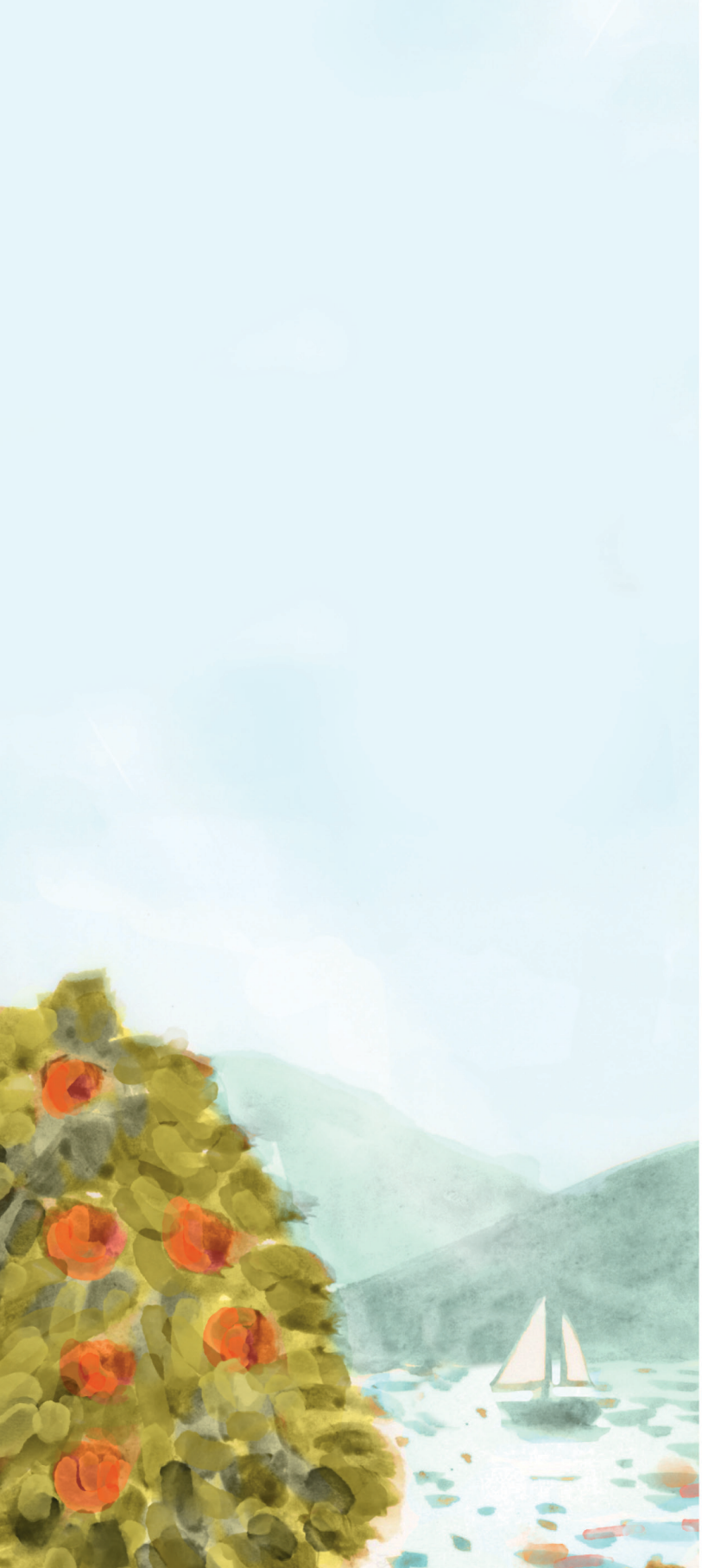

CHAPTER 11

The Post-Venous thromboembolism Functional Status scale: from call to action to application in research, extension to COVID-19 patients, and its use in clinical practice

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Abstract

A broad spectrum of long-term sequelae may be present in venous thromboembolism (VTE) survivors, affecting their quality of life and functioning. To monitor recovery and improve the prognosis of patients with persistent functional limitations, the development of a new outcome measure that could better capture the consequences of VTE was an unmet need. Starting as a call to action, the Post-VTE Functional Status (PVFS) scale was developed to meet this need. The PVFS scale is an easy-to-use clinical tool to measure and quantify functional outcomes after VTE by focusing on key aspects of daily life. As the scale was considered useful in coronavirus disease 2019 (COVID-19) patients as well, the Post-COVID-19 Functional Status (PCFS) scale was introduced early in the pandemic after slight adaptation. The scale has been well incorporated into both the VTE and COVID-19 research communities, contributing to the shift of focus toward patient-relevant functional outcomes. Psychometric properties have been evaluated, mainly for the PCFS scale but recently also for the PVFS scale, including validation studies of translations, showing adequate validity and reliability. In addition to serving as outcome measure in studies, guidelines and position papers recommend using the PVFS and PCFS scale in clinical practice. As broad use of the PVFS and PCFS scale in clinical practice is valuable to capture what matters most to patients, widespread implementation is a crucial next step. In this review, we discuss the development of the PVFS scale and introduction in VTE and COVID-19 care, the incorporation of the scale in research, and its application in clinical practice.

Introduction

A broad spectrum of long-term sequelae including post-thrombotic syndrome (PTS) and post-pulmonary embolism (post-PE) syndrome may occur in venous thromboembolism (VTE) survivors, affecting their quality of life (QoL) and functioning in daily activities.[1-14] Therefore, being able to measure functional status of patients who experienced VTE is key to monitoring recovery and improving the prognosis of patients with persistent functional limitations by targeting their specific needs.

The Post-VTE Functional Status (PVFS) scale was introduced in 2019 as a new tool to quantify functional outcomes in patients with VTE, focusing on relevant aspects of daily life during follow-up after VTE.[15] Integrating such an instrument in VTE care fits well with the increasing recognition of patient-centered outcome measures in clinical practice and the shift toward value-based health care.[16-18] Since it is crucial to gain a better understanding of patients' perspectives and the impact of VTE, there is also the prevailing concept that clinical trials should evaluate outcomes that are most important to patients. Thus far, trials in VTE have focused most frequently (almost exclusively) on objective binary primary outcomes such as bleeding, recurrent VTE, and mortality.[17, 19] Adding patient-reported outcome measures (PROMs) capturing QoL and/or functional outcomes to the primary outcome instead of using PROMs as a secondary outcome or merely an afterthought would broaden the scope of such trials, facilitating translation of the findings of a trial to daily clinical practice.

The aim of this review is to provide an overview of the development of the PVFS scale, the introduction of the scale in VTE and evolution of the scale for application in coronavirus disease 2019 (COVID-19) care, the incorporation of the scale in research and the evaluation of psychometric properties, and transition to clinical practice.

Development of the PVFS scale

The development of the PVFS scale began as a call to action from the need for a new and objective tool to measure functional outcomes in VTE patients.[15] Existing diagnostic and prognostic tools to measure long-term consequences of VTE historically focused on the presence of certain signs and symptoms, such as scales for diagnosis of PTS, rather than on the impact of the consequences of VTE in terms of functional outcomes. Validated questionnaires for assessment of QoL, dyspnea, pain or anxiety did not specifically target functional outcomes either. The development of a new outcome measure that could better capture the full spectrum of the consequences of VTE potentially impacting daily life was an unmet need.

To meet this need, the PVFS scale was proposed in analogy with the modified Rankin Scale that is used to measure functional outcomes after stroke.[15, 20] The PVFS scale was developed for acute pulmonary embolism (PE) and deep vein thrombosis (DVT) aiming at an assessment of individual functional status, as additional instrument on top of the

assessment of the conventional outcomes. Based on input from 18 VTE patients during patient focus group sessions and input from 53 international VTE experts via a Delphi analysis, the scale was further refined.[21] Its final version and relevance were endorsed by both VTE patients and experts.

The PVFS scale is an ordinal scale that captures a full spectrum of functional outcomes in six scale grades, ranging from the absence of any functional limitations and symptoms (grade 0) to severe functional limitations (grade 4) and lastly, death (grade "D"; complete PVFS scale is shown in **Table 1**).[21] The scale covers both limitations in usual activities and duties in daily life, as changes in lifestyle, and helps become aware of functional limitations in patients who experienced VTE. The scale grade "death" was added to allow the scale to be used to measure functional outcome as (primary) outcome in trials and prevents survivor bias. Designed to be assessed at the time of discharge after a VTE diagnosis, after 3 months and optionally after 12 and/or 24 months following VTE diagnosis, multiple assessments of the scale also provide the ability to track functional status over time, and to capture changes in functional status which enables to monitor functional recovery.[22] Consequently, complications after VTE can be detected early. To facilitate comparison between pre-VTE functional status and functional status after the VTE diagnosis, a PVFS scale grade referring to the functional status 1 month prior to the VTE could also be obtained. The PVFS scale can either be self-reported by the patient with the use of an extensive patient questionnaire or a concise flowchart for patient self-report or be assessed during a short, structured interview (resources in **Appendix**). The latter facilitates the assignment of patients to scale grades with reduced subjectivity, which is recommended in the setting of clinical trials. Using the self-reported questionnaire or flowchart, the patient's perspective can be captured during assessment of the consequences of VTE on functional status. An overview of the steps of development of the PVFS scale in shown in **Table 2**.

Table 1: Post-VTE Functional Status scale.[21]

PVFS scale grade		Description
0	No functional limitations	All usual duties/activities at home or at work can be performed at the same level of intensity. Symptoms, pain and anxiety are absent.
1	Negligible functional limitations	All usual duties/activities at home or at work can be performed at the same level of intensity, despite some symptoms, pain, or anxiety.
2	Slight functional limitations	Usual duties/activities at home or at work are performed at a lower level of intensity or are occasionally avoided due to symptoms, pain, or anxiety.
3	Moderate functional limitations	Usual duties/activities at home or at work have been structurally modified (reduced) due to symptoms, pain, or anxiety.
4	Severe functional limitations	Assistance needed in activities of daily living due to symptoms, pain, or anxiety: nursing care and attention are required.
D	Death	Death occurred before assessment.

Abbreviations VTE: venous thromboembolism, PVFS: Post-VTE Functional Status.

Table 2: Overview of the steps of development of the Post-VTE Functional Status scale.

	Steps of development	Status of the PVFS scale	References
1	Review of evidence for functional scales and tools assessing functional status in patients with VTE	✓	[15]
2	Identification of the key characteristics of the modified Rankin Scale for patients with stroke in order to draft measure and item specifications, and fields of applicability which may be relevant for patients with VTE	✓	[15]
3	Assemble a dedicated multidisciplinary work group (including patients, and physicians, nurses, and representatives of major societies) to achieve consensus on the instrument	✓	[21]
4	Formal rounds of review of the proposed categories of the ordinal scale from the dedicated multidisciplinary work group	✓	[21]
5	Formal assessment of reliability and validity of the scale	✓	[21]
6	Next research topics:	Ongoing	
	- Formal assessment of validity and reliability of the scale in clinical trials, including translated versions of the scale into other languages *(face validity, construct validity, concurrent validity)*	✓	PVFS[21, 23] PCFS[24-28]
	- Formal evaluations of assessment methods; blinded versus non-blinded raters, and structured interview versus self-report	Ongoing	PVFS[21] PCFS[28, 29]
	- Assessment of inter-rater agreement of structured interviews	✓	PVFS[21] PCFS[30]
	- Assessment of variability in time of the scale grades following (the intended) timepoints for assessing functional status *(predictive validity)*	Ongoing	PVFS[31-33] PCFS[34-46]
	- Formal assessment of feasibility, e.g. logistics and costs, of the scale in clinical trials	Planned	
	- Relating quality of life and utilities to functional status, with focus on cultural differences	Ongoing	PCFS[25, 28, 47]
	- Evaluation of context- and culture-dependent interpretation of the different categories of functioning	Planned	
	- Relating functional status to relevant long-term endpoints, including economic endpoints (health care utilization, income, benefits use, etc.) and utilities	Planned	
7	Dissemination and implementation in both research protocols and clinical practice for routinely collected data analyses (quality indicator)	Ongoing	PVFS[18, 31, 32, 48, 49] PCFS[34-42, 50-58]

Abbreviations VTE: venous thromboembolism, PVFS: Post-VTE Functional Status, PCFS: Post- COVID-19 Functional Status.

Validity of the PVFS scale

To validate the construct validity of the PVFS scale in patients with VTE, a prospective cohort study of 211 patients was recently performed.[23] Assessed at baseline and at follow-up visit 3 to 6 months after diagnosis of VTE, correlation of the PVFS scale with PROMIS short form physical function (rho -0.67 and -0.63 at baseline and follow-up) and EQ-5D-5L index (rho=-0.61 for both baseline and follow-up) was found to be moderate,

suggesting an adequate construct validity.[23] Also, correlation between PVFS scale and disease-specific QoL questionnaires was evaluated, which was weak to moderate at baseline (rho 0.32 and -0.53 for PEmb-QoL and VEINES-QOL summary scores, respectively) and, more relevant in the setting for clinical trials, moderate to strong at follow-up (rho 0.53 and -0.71 for PEmb-QoL and VEINES-QOL summary scores). Adequate responsiveness was observed, as change over time in PVFS scale grade was significantly associated with corresponding change in PROMIS short form physical function score.[23] During the optimization of the PVFS scale, the inter-rater agreement between patient self-report and assessment via the structured interview, as well as between different raters assigning a scale grade based on the structured interview was shown to be good to excellent (kappa=0.75, 95% confidence interval [CI] 0.58-1.0 and kappa=1.0, 95% CI 0.83-1.0, respectively).[21]

Application of the PVFS scale in COVID-19

Almost 3 years since the outbreak of the COVID-19 pandemic, over 655 million confirmed cases of COVID-19 have been reported globally.[59] Given the large number of COVID-19 survivors recovering from the infection, a great need for reproducible tools to adequately monitor the course of the disease and assess the impact of symptoms on functioning emerged early in the pandemic. Considering the high incidence of acute PE in COVID-19 and occurrence of cardiovascular complications in COVID-19[60-62], we considered whether the PVFS scale was useful in COVID-19 patients as well quite early in the pandemic. Hence, we have pivoted the PVFS scale into the Post-COVID-19 Functional Status (PCFS) scale. After slight adaptation of the PVFS scale (i.e. the wording "VTE" was replaced by "COVID-19"), and consultation with relevant specialists, the PCFS scale was proposed in a letter to the editor to measure functional status after severe acute respiratory coronavirus 2 (SARS-CoV-2) infection and monitor functional recovery of COVID-19.[63] Fully aware of limitations of an adaptation developed for a different setting, we believed that the clinical similarities and the pressing circumstances justified this proposal as it would help identify patients with poor or worse functional outcome or incomplete recovery, which could help guiding efficient use of resources in post-COVID-19 care. The PCFS scale is intended to be assessed at the time of hospital discharge, in the first weeks after discharge to monitor direct recovery (e.g. 4- and 8-weeks post-discharge), and 6 months after COVID-19 diagnosis to evaluate the presence and degree of persistent functional disabilities, as described in the manual (resources in **Appendix**).[64] Further justification for the use of an ordinal outcome came from the COVID-19 blueprint of the World Health Organization (WHO), which also proposed an ordinal scale as the outcome for early acute treatment trials.[65]

During the COVID-19 pandemic, lack of resources could have contributed to suboptimal use of the scale. Therefore, we set out to investigate the implementation and application of the PCFS scale in research projects and clinical practice by conducting interviews and a questionnaire among users of the PCFS scale known to the authors. Semi-structured interviews about use of the PCFS scale were conducted with health-care professionals and researchers, representing different settings in which the PCFS scale was applied such as clinical trials or observational studies, and clinical practice including rehabilitation setting, outpatient clinic and hospital ward. The questionnaire was distributed among PCFS collaborators to elicit their experience with use of the scale. A full report on the findings can be found on our PCFS resource page, with its highlights further summarized below.[66]

Seven interviews were conducted by one researcher (Y.N.J.L.). The majority of the interviewees used the PCFS scale in combination with other validated instruments, and all believed that the PCFS scale is easy to use. It was mentioned that using the PCFS scale alone could be insufficient; the scale should be used in combination with other outcome measures such as scores that assess symptom burden or QoL. It was also noted that pre-existing functional limitations before SARS-CoV-2 infection (e.g. mobility issues and wheelchair use) are not taken into account. Assessment of a pre-COVID-19 scale grade reflecting functional status prior to COVID-19 could be a solution to this, by allowing changes in functional status after the infection to be recorded.

After approaching 100 research groups who had been in touch with the PCFS principals for more information on the PCFS scale to participate in the survey, 65 participants responded and 54 participants completed the questionnaire of whom 39 used the scale in research (17/39) or clinical settings (4/39), or both (18/39). Of those participants, 67% reported to be using the patient-reported questionnaire for assessment of the PCFS scale, 51% the structured interview and 33% the flowchart for patient self-report. According to the experiences of the participants, 51% had encountered application of the scale by researchers, 41% by physicians, and 31% by patients themselves through self-report. On a scale from 0 (disagree) to 10 (agree), the participants reported a median of 8 for the statements "easy for physicians to use and understand" and "recommend the scale to other colleagues", and a median of 10 for the statements "easy for patients to use and understand" and "useful as a tool in the SARS-CoV-2 pandemic". These ratings confirm that the PCFS scale is useful and easy to apply and interpret.

Validity of the PCFS scale

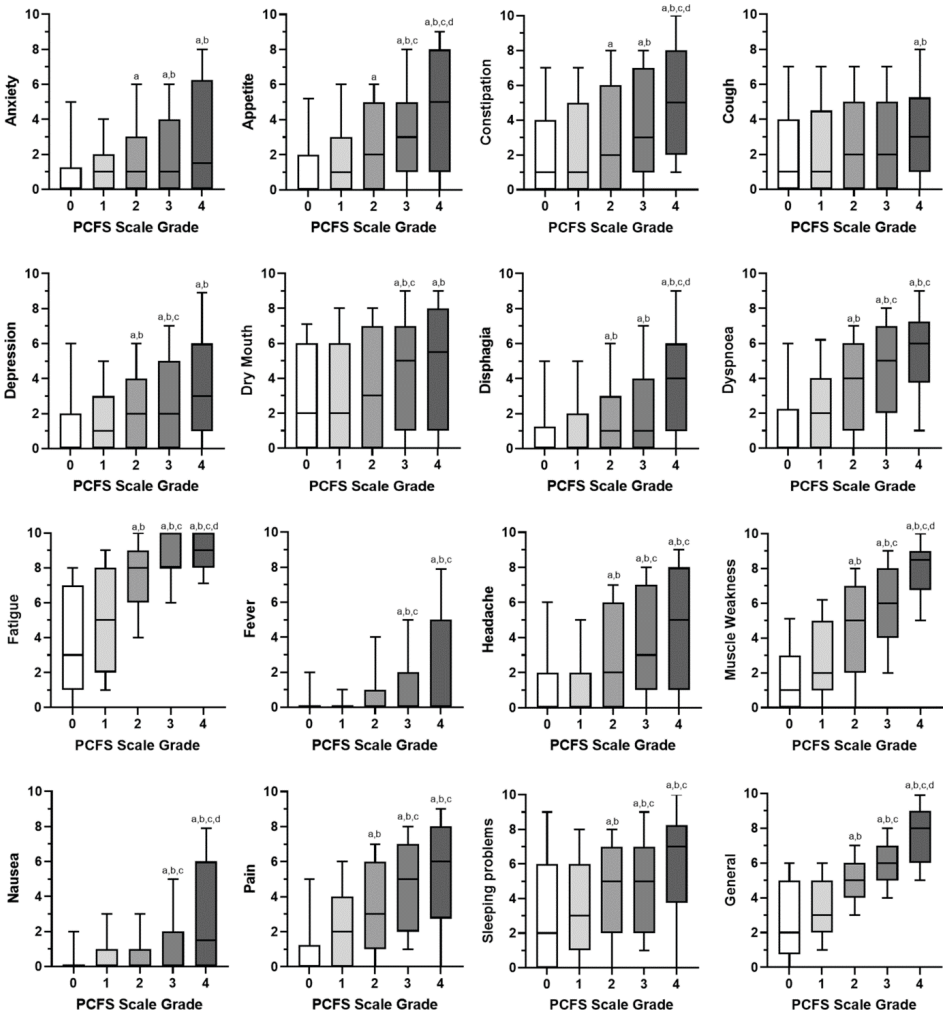
As the entire research community shifted focus to COVID-19 during the last years, there was focus on the PCFS scale as well. We first provide an overview of the evidence

obtained from PCFS studies and then extrapolate to the PVFS scale. The construct validity has been demonstrated for the first time among 1939 adult self-selected individuals with confirmed and presumed COVID-19 at 3 months after symptom onset.[24] For increasing PCFS scale grades from grade 2 upward (e.g. worsening of functional status: slight, moderate to severe functional limitations), individuals were found to have a gradual rise in number and intensity of symptoms (**Figure 1**) as well as in impairment in work and activities assessed using the Work Productivity and Activity Impairment questionnaire. Also, a decrease in health-related QoL based on the EuroQoL 5-dimension 5-level (EQ-5D-5L) index was found, with weak to strong correlation between functional status and the EQ-5D-5L QoL domains (rho=0.23-0.66; strongest correlation with the "usual activities" domain).[24] In a cross-sectional study in which 133 COVID-19 patients were evaluated at hospital discharge, the PCFS scale was able to discriminate between increasing symptoms of fatigue and decreasing health-related QoL as well as functional performance.[47] In a multivariable analysis, the length of in-hospital stay was found to be associated with worse functional status.[47] In a cohort of 121 COVID-19 survivors who were evaluated 2 to 9 months after hospitalization, the PCFS scale correlated moderately to strongly with the Short Form-36 questionnaire (SF-36; rho -0.71 and -0.43 for physical and mental scores, respectively), Hospital Anxiety and Depression Scale (HADS) (rho 0.39 and 0.62 for anxiety and depression scales), modified Medical Research Council dyspnea scale (mMRC; rho=0.53), and Borg dyspnea scale after 6-minute walk test (rho=0.48).[25] No correlations between PCFS scale and diffusing capacity for carbon monoxide or persistent abnormalities on chest computed tomography were found.[25] In 95 COVID-19 survivors who had no functional limitations (PCFS scale grade 0) 1 month before onset of COVID-19 symptoms, the inter-rater reliability of the structured interview, assessed by two authors at 6 months after discharge, was good at baseline and after 6-month follow-up (kappa=0.68, 95% CI 0.46-0.90 and kappa=0.79, 95% CI 0.65-0.93, respectively).[30, 67] The PCFS scale has also been used in a validation study of a new set of tools developed for monitoring consequences of long COVID, to examine the relation between the novel long COVID Symptom and Impact Tools (ST and IT) and functional status according to the PCFS scale.[26] Moderate correlation was found (rho -0.39 and -0.55 for long COVID ST and IT scores).

Over time, the PCFS scale has been translated into more than 25 languages available under an open access license (Creative Commons Attribution 4.0 International Public License; resources in **Appendix**). Some of these were the result of formal cross-cultural adaptation studies, and several validation studies of varying quality and

focus have been published as part of the translation process.[27-29, 68-71] The first study, describing the translation and cultural adaptation to Colombian Spanish performed by two bilingual translators whose native language was Spanish followed by review by eight postgraduate experts involved in COVID-19 patient-care, was published at the beginning of 2021.[68]

Figure 1: Symptom intensity according to functional status expressed by Post-COVID-19 Functional Status scale.



From Machado et al. Health Qual Life Outcomes 19, 40 (2021)[24]; permission for reuse under open access license, http://creativecommons.org/licenses/by/4.0/.

Abbreviations COVID-19: coronavirus disease, PCFS: Post-COVID-19 Functional Status.

In terms of construct/concurrent validity, correlation between the PCFS scale and other scales was assessed in studies evaluating the Spanish and Turkish version of the PCFS scale: correlations with EQ-5D-5L index and Global Activity Limitation Indicator were high, and moderate with HADS scores,[28] correlation with the mMRC dyspnea scale was moderate and ranged from rho=0.28 to 0.43 for subscores of the London Chest Activities of Daily Living scale[27], and correlation with the Barthel Index for Activities of Daily Living was low.[27,28] In the cross-sectional validation study of the Spanish translation, test-retest reliability was substantial (kappa=0.63, 95% CI 0.52-0.74). Also, the questions in the Mexican Spanish version of the scale were found to measure the same aspects of functional status, with the structured interview coming out as best (Cronbach's alpha 0.84 and 0.67 for structured interview and self-reported questionnaire, respectively),[29] and reliability of the Chilean Spanish version was demonstrated in a cross-cultural adaptation and validation study.[69, 70] In India, an ongoing study is evaluating the validation of the PCFS scale translated and adapted to Kannada language.[71]

The results of the validation studies suggest that the scale captures a patient's well-being and physical state. Strongest correlations were found with the EQ-5D-5L "usual activities" domain and SF-36 physical score, confirming that the scale can be used to measure functional status. While face validity, construct validity, and concurrent validity indeed have been studied, predictive validity (i.e. the usefulness of the scale in clinical prediction relevant to the patient or medical professional) has so far been understudied. These types of studies require a longer follow-up, as well as data from other sources (such as administrative data and data on health care utilization), which are currently slowly becoming available for the PCFS scale.

Lessons from the PCFS scale for the PVFS scale

The COVID-19 research community responded positively to the PCFS scale and the scale was taken up well. Although predictive validity has so far been understudied, multiple studies exploring the scale's usefulness and evaluating different types of validity showed that the PCFS scale appears to measure what it aims to measure and that the scale corresponds reasonably to other relevant outcomes, especially when assessed through a structured interview. We must acknowledge that these studies have been conducted under tremendous time pressure and with limited resources. Future studies should focus on using solid methodologies and should go beyond cross-sectional designs. When designing new studies, some methodological aspects related to the use of the scale could be better taken into account, such as making sure that assessment of the scale is performed at one specific moment during follow-up with a tight time window,

and inclusion of the sixth scale grade ("death") to not only focus on survivors and thus prevent selection bias. Furthermore, the timing of assessment of the PCFS scale in the first weeks post-discharge (e.g. after 4 weeks as mentioned in the manual) may be too early after discharge. As widespread use of the PVFS scale in VTE clinical practice and studies is still ahead of us, these lessons can be learned from use of the PCFS scale, which has all in all proven to be useful in studying COVID-19.

Based on this, there is enough supporting evidence for the PCFS and by extension the PVFS scale to be integrated as additional outcome measures in clinical practice and research settings. Indeed, multiple studies have included the PCFS or PVFS scale as an outcome measure. The PCFS scale is being used in diverse COVID-19 and VTE research projects, including (ongoing) clinical trials and observational studies across the world, such as the OVID randomized trial studying primary thromboprophylaxis in high-risk outpatients with COVID-19.[33-46, 55-57, 72-75] For post-PE care specifically, the PVFS scale is included in the study protocols of the large Pulmonary Embolism International THrOmbolysis (PEITHO)-3, Higher-Risk Pulmonary Embolism Thrombolysis (HI-PEITHO), and SAFE-SSPE (Surveillance versus Anticoagulation For low-risk patiEnts with isolated SubSegmental Pulmonary Embolism) randomized controlled trials, to measure functional status at different timepoints during the follow-up period as one of the secondary outcomes.[31, 32, 49] Future VTE trials may sometime evaluate functional outcome as (co) primary outcome, following the example of the modified Rankin Scale, which is the most prevalent functional outcome measure used in stroke research.[76]

Clinical application

Not only have the PVFS and PCFS scales been applied in studies to evaluate psychometric properties or to serve as outcome measures, the scales are also recommended in guidelines and position papers to be used in clinical practice. The PCFS scale is recommended in the Chilean national interdisciplinary consensus guidance on revalidation after COVID-19, the German guideline on diagnostics and treatment strategies in long COVID, and a clinical guidance document for follow-up and care of patients with persistent symptoms after COVID-19 published by the Catalan Health Service.[50-52, 58] Also, a consensus statement on post-COVID-19 physiotherapy for the Indian context recommends the PCFS scale as an outcome measure to monitor progress in post-COVID-19 rehabilitation.[53] In addition, the WHO guideline on clinical management of COVID-19 patients was published in September 2022, which includes the PCFS scale.[54] The scale is described in the section on referral of adults with post-COVID-19 condition for rehabilitation as a validated instrument to assess functional

status, endorsing the usefulness of the scale in practice. Lastly, the position paper of the European Society of Cardiology on optimal follow-up after acute PE, endorsed by the European Respiratory Society, includes the recommendation to assess the presence of functional limitations and chronic symptoms in a standardized manner with the use of validated tools, mentioning the PVFS scale as such a tool.[48]

Recently, a standardized set of outcome measures for patients with VTE has been developed, with outcomes and outcome measures selected by international patient representatives and VTE experts through a modified Delphi process.[18] This consensus recommendation includes the outcomes that are deemed most important to patients with VTE to measure during follow-up after the VTE diagnosis. One of the core outcomes considered important is functional limitations, which is recommended to be measured by the PVFS scale.[18] Integration of patient-reported outcome measures such as the PVFS scale in clinical practice is believed to improve care for VTE patients and to contribute to the delivery of value-based health care. Furthermore, routine use of such measures will empower patients to be actively engaged in the management of their disease. With the development of this standardized set, the first steps toward patient-centered care have been taken, leading to implementation being the next important step. As the scale is a brief tool that is easy to use and interpret, it is considered to offer great potential when it comes to implementation of patient-reported instruments in daily practice.[77]

The PCFS scale was included as a potential outcome measurement instrument in a similar Delphi process (Post-COVID-19 Condition Core Outcome Set [PC-COS] study, available via PC-COS.org), as it was thought to measure relevant outcome domain(s) part of the core outcome set developed for post-COVID-19 condition.[78] However, no consensus was reached, for multiple domains, as to which tool was best to assess these domains. The PCFS scale was ultimately not included as one of the recommended instruments to assess multiple domains, as preference was given to more established tools such as the SF-36, EQ-5D and WHO Disability Assessment Schedule 2.0. Novel COVID-19 specific tools that were noted are the COVID-19 Yorkshire Rehabilitation Screening scale and the Symptom Burden Questionnaire for Long COVID. Despite their names, both instruments are scores only, thus leaving out some of the methodological advantages of using an ordinal outcome. A reason why the PCFS scale was not included might be that these instruments were developed from scratch, while the PCFS scale is based on the PVFS scale which affected the formal evaluation within the Delphi/COSMIN (COnsensus-based Standards for the selection of health Measurement INstruments) process. Ultimately, the PC-COS study group describes that "At the online consensus meeting, there was a very high level of support for future research focused on a consensus process regarding use

of existing outcome measurement instruments versus long COVID-specific instruments, versus a combination of both types of instruments for post-COVID-19 condition/long COVID research and clinical practice," a statement adequately describing the path toward more evidence and experience to measure the long-term effects of COVID-19.

Conclusion

Starting as a call to action, the PVFS scale was developed to meet the need for a tool to measure and quantify functional outcomes after VTE, to capture the impact of persistent symptoms on functioning. Early in the COVID-19 pandemic, the scale was considered to be useful in COVID-19 patients as well, leading to the introduction of the PCFS scale. The PVFS and PCFS scale have been well incorporated into both the VTE and COVID-19 research communities. Psychometric properties have been evaluated in several studies, mainly for the PCFS scale but recently also for the PVFS scale, showing adequate face validity, construct validity, concurrent validity and reliability. Clinical studies, both completed and ongoing, have included the PVFS and PCFS scale as an outcome measure, which contributes to focus on patient-relevant functional outcome in addition to conventional outcomes. Consistent with the increased appreciation of patient-centered outcome measures, broad use and implementation of the PVFS and PCFS scale in clinical practice is valuable to capture what matters most to patients.

Appendix

List of resources

Post-VTE Functional Status (PVFS) scale:

Appendix C "Manual to the Post-VTE Functional Status scale for the structured interview as well as for the patient self-report - version December 2019." Available via: Boon GJAM, et al. Measuring functional limitations after venous thromboembolism: Optimization of the Post-VTE Functional Status (PVFS) Scale. Thromb Res. 2020 Jun;190:45-51. doi: 10.1016/j.thromres.2020.03.020. Epub 2020 Mar 30. PMID: 32298840.

Post-COVID-19 Functional Status (PCFS) scale:

The structured interview and materials intended to facilitate the self-reported assessment can be found in the published manual, which is free of charge available on the PCFS resource page on OSF, accessible via https://osf.io/qgpdv/. Translations of the PCFS scale manual can be found on the PCFS resource page as well.

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