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Validation of the Pulmonary Arterial Hypertension-Symptoms and Impact for Clinical Use (SYMPACT-CP): a qualitative interview study

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Abstract

Background The Pulmonary Arterial Hypertension-Symptoms and Impact (PAH-SYMPACT) questionnaire is a patient-reported outcome measure designed to assess pulmonary arterial hypertension (PAH) symptoms and impacts in clinical trials. It includes recall periods of 24 h for symptoms and 7 days for impacts. The PAH-SYMPACT for use in Clinical Practice (SYMPACT-CP) is an adaptation of the PAH-SYMPACT in which the recall period for symptoms has been revised to 7 days, a timeframe more appropriate for clinical practice settings. The PAH-SYMPACT was psychometrically validated previously. As such, this study focused on assessing whether patients with PAH can use the SYMPACT-CP appropriately to rate their symptoms over the 7-day range, and it explored their perspectives on the utility and feasibility of completing the questionnaire as part of routine clinical assessments.

Methods This was a cross-sectional, noninterventional, qualitative study involving one-on-one telephone interviews with English-speaking adults (≥ 18 years) living in the US diagnosed with PAH. Participants were provided copies of the SYMPACT-CP to review, and interviews were subsequently conducted using a semi-structured guide including concept elicitation and cognitive interviewing sections. Transcripts were coded using a coding framework based on the interview guide.

Results Fifteen participants were interviewed (mean age, 49.9 years; $n = 13$ female, $n = 13$ White). Most ($n = 12$) stated that they thought about the last 7 calendar days or the "last week" when asked to interpret the 7-day recall period and all but one ($n = 14$) could easily remember their symptoms over this period. All 15 participants reported that it would be easy to fill out the SYMPACT-CP prior to a clinic visit with their physician or other healthcare provider (HCP), and most ($n = 14$) felt it would be useful in the management of their disease. Participants felt that breathing difficulties ($n = 11$), followed by swelling ($n = 4$), feeling lightheaded, dizzy, or faint ($n = 3$), and heart palpitations/heart fluttering ($n = 3$) were the most important symptoms to share with their HCPs.

Conclusions The SYMPACT-CP is valid to assess symptoms and impacts of PAH in clinical practice. Compared with the PAH-SYMPACT, it provides a consistent 7-day recall period for symptoms and impacts and may improve symptom monitoring and disease management during clinical appointments.

Keywords Pulmonary arterial hypertension, PAH-SYMPACT, SYMPACT-CP, Qualitative research, Patient-reported outcome, Symptoms, Clinical practice

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Introduction

Pulmonary arterial hypertension (PAH) is a life-threatening progressive condition that causes pulmonary vascular remodelling and often leads to right heart failure and death [1, 2]. Estimates from a recent systematic review of registry data indicate a PAH incidence of approximately 6 cases/million adults and a prevalence of approximately 48–55 cases/million adults [3]. Diagnosis is usually delayed due to the non-specific symptoms of PAH [4] after diagnosis, the current median survival is about 6 years [5, 6]. Multiple factors underlie the progressive nature and risk assessment in PAH [1]. Patients with PAH present high unmet needs as disease management is complex [1]. PAH interferes with all aspects of patients' daily lives by causing breathlessness, fatigue, and lack of energy, making even the simplest tasks difficult, which can lead to feelings of isolation, anxiety, stress, and depression [2, 7].

Guidelines highlight that patient-reported outcome (PRO) measures have the potential to assist in the management of the disease by providing valuable insight from patients' own experiences [2, 8, 9]. PROs developed specifically for PAH have greater coverage of patient-relevant symptoms and impacts than generic PROs, and they can be used to monitor functional status, prognosis, and health-related quality of life [2]. However, to date, only one PAH-specific PRO has been developed according to regulatory and scientific best practices that captures disease-related changes relevant to patients: the Pulmonary Arterial Hypertension-Symptoms and Impact (PAH-SYMPACT®). The PAH-SYMPACT is a psychometrically validated disease-specific PRO measure that assesses symptoms associated with PAH and their impacts in adults [10]. It was originally developed for and has been used in many clinical trials of pulmonary hypertension [11–14]. The PAH-SYMPACT includes an oxygen use item and 11 symptom items along with 11 impact items, each scored on a 5-point Likert scale (0 = "no symptom" to 4= "very severe") [10, 15]. Recall periods are 24 h for symptoms and oxygen use and 7 days for impacts [10] (Fig. 1, Table 1). Use of the instrument in PAH as well as other pulmonary hypertension indications has been supported by the European Medicines Agency, who also encouraged further investigation and development of the instrument [16].

While healthcare providers (HCPs) may be interested in using the PAH-SYMPACT to manage their patients'

Table 1 Similarities and differences between PAH-SYMPACT and SYMPACT-CP

Characteristics	PAH-SYMPACT	SYMPACT-CP
Recall period		
PAH symptoms	24 h	7 days
PAH impacts	7 days	7 days
Setting for use	Clinical trial	Clinical practice/research

Abbreviations: *PAH-SYMPACT* Pulmonary Arterial Hypertension–Symptoms and Impact, *SYMPACT-CP* Pulmonary Arterial Hypertension-Symptoms and Impact for use in Clinical Practice

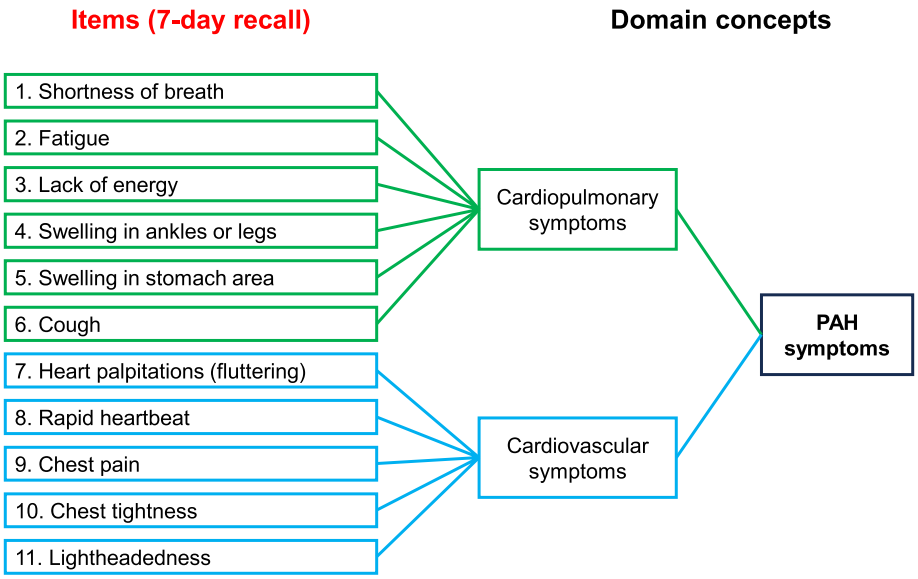

Fig. 1 Conceptual framework of the SYMPACT-CP symptom domains. For clarity, the oxygen use and impact items in the SYMPACT-CP are omitted from the diagram as study participants were only asked to review symptom items. Abbreviations: PAH: pulmonary arterial hypertension, SYMPACT-CP: Symptoms and Impact for Use in Clinical Practice

disease, this instrument was not designed for use in clinical practice. In particular, the 24-h recall period for symptoms does not support symptom monitoring in a way that can sufficiently inform HCPs about their patients' experiences with PAH and support their conversations with patients. In addition, the symptom items need to be completed daily for 7 days [10], but repeated daily assessment may be impractical in clinical practice. The Pulmonary Arterial Hypertension-Symptoms and Impact for use in Clinical Practice (SYMPACT-CP), is an adaptation of the PAH-SYMPACT for use in routine clinical practice. In the SYMPACT-CP, the 24-h recall period for the oxygen use item and the 11 symptom items has been changed so that the entire measure has a 7-day recall period (Fig. 1, Table 1). This provides a potential advantage for use in clinical practice. The psychometric properties of the PAH-SYMPACT have been validated previously; therefore, this analysis focused on assessing the content validity of the SYMPACT-CP to ensure its relevance and applicability in a clinically relevant population. Here, we conducted concept elicitation and cognitive interviews of adults with PAH to examine their ability to aggregate their symptom experience over a 7-day recall period and to explore their perspectives on the utility and feasibility of completing the SYMPACT-CP as part of a routine clinical assessment.

Method

Study design

This was a cross-sectional, noninterventional, qualitative interview study involving one-on-one telephone interviews with English-speaking adults (≥ 18 years) living in the US diagnosed with PAH. The study was performed in accordance with the provisions of the Declaration of Helsinki, International Conference on Harmonization Guideline for Good Clinical Practice, Good Pharmacoepidemiology Practice, and the applicable legislation on Non-Interventional Studies and/or Observational Studies. It was approved by the Western-Copernicus Group institutional review board (no. 20225418). Participants were recruited through a third-party vendor. To be eligible, participants had to provide confirmation of a PAH diagnosis via right-heart catheterization and symptomatic disease in line with a World Health Organization Pulmonary Hypertension Functional Classification (WHO FC) of II, III, or IV [17]. Participants also had to provide informed consent and be willing to be audio-recorded.

Eligible participants completed an online questionnaire to collect sociodemographic and clinical data before the interviews. Participants were sent a copy of the SYMPACT-CP in a sealed envelope or via email. Participants were instructed by the interviewer to open and review the questionnaire prior to completing the interview, but they were asked not to do so until instructed. Interviews lasted approximately 60 min and were conducted via teleconference by experienced scientific staff trained in qualitative data collection (Table S1), who used a semi-structured qualitative interview guide including open-ended questions (Table S2).

The semi-structured qualitative interview guide included a concept elicitation section designed to assess participants' general experience with PAH and explore their recall of PAH symptoms over the previous week. During this portion of the interview, participants described their experiences discussing their PAH symptoms with their HCP, such as the symptoms they typically did or did not share with their HCP, as well as symptoms that their HCP typically asked them about during appointments. The interviewer then probed participants to describe the most important symptoms they felt should be discussed with their HCPs. If participants did not spontaneously mention which PAH symptoms or impact concepts they experienced, the interviewer probed further.

Because the impact items in SYMPACT-CP were originally developed and validated with a 7-day recall period in PAH-SYMPACT [10], they did not need to be debriefed for this study. Therefore, the cognitive interview portion of the study focused exclusively on the symptom items with a modified 7-day recall period. Participants were asked about individual symptom items, which answer they chose on the SYMPACT-CP item, and how they arrived at their choice. Participants were also asked about their understanding of the 7-day recall period, whether any aspects were difficult to understand or confusing, and whether they would recommend any changes. Finally, participants were asked about the usefulness of the SYMPACT-CP, including their expectations for how HCPs might use the information obtained and whether they thought the measure would be valuable to complete and share with HCPs as part of routine clinic visits.

Per standard practice, participants received compensation of $125 in cash/cash equivalent at the end of each interview.

Analysis

Audio-recorded data were transcribed by a third-party professional transcription service. All personally identifiable information and protected health information were removed. Cleaned, anonymised audio transcripts were coded by two scientific staff (RT, BS) in ATLAS.ti v22 (ATLAS.ti Scientific Software Development GmbH, Germany) using a coding framework based on the interview guide. Concept codes were developed to capture

descriptions of participants' PAH symptoms, their perspectives on SYMPACT-CP and aspects related to individual SYMPACT-CP items, and their views on the utility of completing it prior to an HCP appointment. The results were summarised in quote tables and code frequency/summary tables. Concepts with frequencies ≥20% were prioritised for review. Sample sizes and denominators in text refer to the number of participants who answered each question, unless otherwise specified.

Results

Sample

Fifteen adults with PAH were interviewed between December 22, 2022, and February 9, 2023. Participants were on average 49.9 years of age (standard deviation, 12.9; range 30–71) (Table 2). Most participants were female ($n=13$), White ($n=13$), and married ($n=9$). All participants had completed at least secondary/high school. Most participants had a self-reported WHO FC of II ($n=8$) or III ($n=6$); a single participant had a WHO FC of IV. Most ($n=11$) had mild pulmonary hypertension symptoms in the past 7 days, and many rated their overall health as "good" ($n=8$) or "fair" ($n=5$). The range of participants' responses to the 11 symptom items are summarized in Tables S3–S13.

Table 2 Participant characteristics

Characteristic	Total sample *N* = 15
Age (years), mean (SD)	49.9 (12.9)
Gender, *n* (%)	
Male	2 (13)
Female	12 (80)
Self-describe as female	1 (7)
Race, *n* (%)	
White	13 (87)
Black or African American	2 (13)
Ethnicity, *n* (%)	
Hispanic or Latinx	2 (13)
Not Hispanic or Latinx	13 (87)
Highest level of education completed, *n* (%)	
Associate degree, vocational, technical, or trade school	4 (27)
Some college (< 1 year)	3 (20)
Some college (2–3 years)	3 (20)
University/college degree	1 (7)
Postgraduate degree	4 (27)
Marital status, *n* (%)	
Married	9 (60)
Single	2 (13)
Divorced/separated	3 (20)
Widowed	1 (7)
Employment status, *n* (%)	
Employed, full-time or part-time	4 (27)
Homemaker	3 (20)
Unemployed	1 (7)
Retired	2 (13)
Disabled	5 (33)
Severity of pulmonary hypertension symptoms in the past 7 days, *n* (%)	
Mild	11 (73)
Moderate	3 (20)
Severe	1 (7)
WHO FC (self-reported), *n* (%)	
Class II	8 (53)
Class III	6 (40)
Class IV	1 (7)
Self-rated general health, *n* (%)	
Very good	1 (7)
Good	8 (53)
Fair	5 (33)
Poor	1 (7)

Abbreviations: *SD* Standard deviation, *WHO FC* World Health Organization Functional Classification

Concept elicitation results

Most participants reported that the items in the SYMPACT-CP were relevant based on their experience with PAH. When asked about their symptom experience, participants noted that they discussed an average of three symptoms (range 2–6) with their HCP during a routine clinical visit. The most frequently discussed symptoms related to difficulties with breathing and shortness of breath (13/15), swelling/edema (5/15), and fatigue/tiredness (5/15) (Fig. 2) When participants were asked about the PAH symptoms they felt were most important to discuss with their HCPs, they mentioned an average of two symptoms (range 1–4) as "most important." Breathing difficulties (shortness of breath) (11/15) and swelling (4/15) were the symptoms considered most important to discuss with physicians (Fig. 2). Participants also described symptoms related to feeling lightheaded, dizzy, or faint (3/15) and heart palpitations/heart fluttering (3/15) as important to share with their HCPs. Two participants noted that discussing any new or changes in symptoms (for example, "an increase in heart palpitations from the last appointment") was important. They mentioned that it would be important to tell HCPs about new symptoms like "fainting," "heart palpitations," "chest discomfort," "shortness of breath," "fluid retention," "swelling," or "rapid weight gain." One participant who reported discussing four symptoms during their medical appointments stated that it was important to share all symptoms, including fatigue, with their HCP. One participant shared that the 7-day window could help them remember symptoms for discussion at the doctor's visit, because they typically visit their doctor every 6 months.

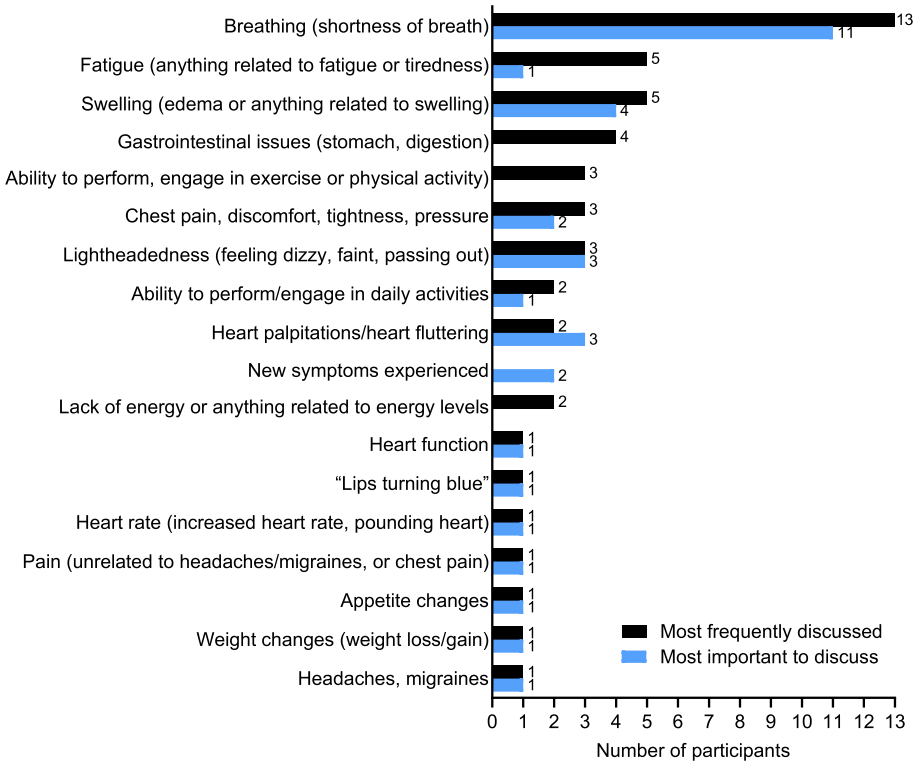

Fig. 2 Elicited symptoms, impacts, and side effects. In the concept elicitation portion of the study, all 15 participants were asked to describe the symptoms they discussed most frequently with their healthcare providers and those that they found most important to discuss. Number of participants shown on bars

Finally, while most participants (9/15) reported sharing all the symptoms they experienced with their HCP, two participants indicated that they do not typically discuss fatigue and pain with their HCPs. Reasons for not discussing a symptom included feeling that it was obvious or not related to PAH or that it was a side effect of treatment. These results suggest the items were relevant to participants based on their experience with PAH. Participants also mentioned impacts related to cognition, mood, sleep, appetite, productivity, physical activity, and side effects of medication. While these concepts were missing from the questionnaire that participants reviewed, many (such as cognition and mood) are covered by the already validated impact items of the SYMPACT-CP and others (such as productivity and medication side effects) may be assessed with other PROs.

Cognitive interview results

Participants demonstrated clear understanding of the instructions and recall period. When participants were asked to freely describe the time period they thought about when selecting responses to the SYMPACT-CP, all but one provided clear responses. Most (12/14) stated that they thought about "the last seven days" or the "last week." One participant (1/14) reported thinking about their symptoms over the "last few days" and another (1/14) reported thinking of their symptoms "today" (Table 3). Participants were also asked about how easy or difficult it was to recall their PAH symptoms over the 7-day recall period. All but one participant (14/15) recalled their symptoms with ease, and most (10/14) used terms such as "easy," "pretty easy," or "very easy." Among these participants, some (4/10) specifically stated that it was easy to recall their symptoms over this time because their symptoms affected them on a regular basis. Another two of these participants (2/10) experienced unusual life circumstances that made them more aware of their symptoms, such as travelling while on vacation or being unusually busy due to holidays. One participant (1/15) reported that the recall period was "pretty hard" because of being busy, although this participant generally described the 7-day recall period as "easy" while discussing individual SYMPACT-CP items.

Participants were queried on the potential utility of the SYMPACT-CP, specifically the usefulness of completing the questionnaire prior to HCP visits and their expectations on how their HCP would use this information. All 15 participants reported that it would be easy

Table 3 Sample participant quotes about the 7-day symptom recall period for the SYMPACT-CP

Question	Timeframe/ease of recall	Illustrative quotes
What exact period of time did you think about as you were selecting your answer?	"Last week" or "last 7 days"	001–011/WHO FC II: *"I went Tuesday to Tuesday. Previous Tuesday until yesterday."* INTERVIEWER: *"You were thinking about the specific days of the week and working backwards with seven days."* 001–011/WHO FC II: *"Yes."*
		001–009/WHO FC II: *"I would have thought about exactly in the past 7 days, not like last week or something like that."*
		001–013/WHO FC III: *"The day that I answered it, I thought about that day and 6 days prior, so for an entire week."*
	"Today"	001–004/WHO FC II: *"When I was looking at the answers, I was thinking about today."*
	"Last few days"	001–006/WHO FC III: *"I was thinking about the last few days. Like over a period of 2 or 3 days before I was actually answering the questions."*
In general, how easy or difficult was it for you to remember your experience with these PAH symptoms over the past 7 days?	Easy or very easy	001–007/WHO FC II: *"Very easy. Because these symptoms are something that occur every day, all the time. It's like you can't have this disease and forget you have this disease."*
		001–009/WHO FC II: *"…I would feel like it's pretty easy. This is a disease that I live with every single day, and it impacts different things I do in different ways every single day, so whether I'm asking questions or not, I'm definitely thinking about it, and I definitely remember. You know, "I was really tired this day," or "This day was really hard." It's pretty easy for me to remember those things."*
		001–013/WHO FC III: *"It was easy. I was just coming back from a cruise. Walking around the ship, going out on excursions and stuff, I can remember what I couldn't do and what I could do because of it, so it was pretty simple for me."*
		001–003/WHO FC II: *"Very easy. Because I am at a higher elevation, I think I'm very aware."*
	Difficult	001–002/WHO FC II: *"Honestly, pretty hard. Thankfully, I'm still a busy person, so for me to go back 7 days is pretty hard. So I just kind of tried my best to kind of put everything together and answer the questions."*

Abbreviations: *PAH* Pulmonary Arterial Hypertension, *SYMPACT-CP* Symptoms and Impact for Use in Clinical Practice, *WHO FC* World Health Organization Functional Classification

to complete the SYMPACT-CP prior to a visit with their HCP, and most (14/15) felt it would be useful in the management of their disease (Table 4). Of the 14 participants who felt that the SYMPACT-CP would be useful, many (9/14) explained that it could serve as a "checklist" for forgotten symptoms or a reminder of symptoms they wished to discuss with their doctor. Most participants expected their HCPs to use their SYMPACT-CP scores to track symptom progression (10/15) and/or adjust their medication or treatment schedule (8/15). The participant who did not feel the SYMPACT-CP would be useful stated that they hoped their doctor would be able to assess their symptom severity without a scoring system. One participant had their own approach to PAH symptom tracking, using a personal journal, but other participants (9/14) stated the SYMPACT-CP could "help other patients," "prompt me to remember or mention something that is happening," "save time," or "make it easy for doctors."

Discussion

The PAH-SYMPACT was designed to assess PAH symptoms (24-h recall period) and impacts (7-day recall period) [18]. The 24-h recall period was selected to monitor symptoms in clinical trials but is not suited for use in clinical practice where repeating assessments daily for 7 days is impractical. The SYMPACT-CP is an adaptation of the PAH-SYMPACT in which the recall period for symptoms has been modified to 7 days so that it can be used to inform HCPs about their patients' experiences with PAH in a clinical practice setting. This study confirmed the validity of the 7-day recall period for clinical practice: patients clearly understood the 7-day recall period, and they considered their symptom experiences easy to recall over 7 days. Of note, several participants noted that the ease of using this recall period was related to the symptoms affecting them on a regular basis. In agreement with findings using the PAH-SYMPACT [10, 18], this study found that prominent symptoms shared

Table 4 Sample participant quotes about the utility of the SYMPACT-CP

Concept	Illustrative quotes
Ease of completion prior to visit with doctor or HCP	001–005/WHO FC II: "*I think it would be easy.…I may not have thought about the fact that I had two episodes where I was lightheaded and needed to sit and give my body time to recover unless it was—that may prompt me to remember, I needed to mention that this is something that's happening, and it hasn't been happening and now it is.*"
	001–006/WHO FC III: "*It would be easy…in the sense that I could answer the question. I'll have to think about it, but I think it could be important, so yes, it would be easy. I would be willing to do it.*"
Usefulness of completing prior to visit with doctor or HCP	001–012/WHO FC III: "*It'd be easy, and it would probably be pretty helpful because…he just sees me every six months and once a year runs a test, so when I see him and there isn't a brand-new symptom, then we don't really talk about symptoms.*"
	001–002/WHO FC II: "*I think it would be useful because sometimes the doctor comes in and I feel like I just forget what I was going to ask him, whether it's rapid heartbeat or I had swelling on Tuesday, sometimes I forget because I'm bombarded with different questions. So I feel like this would be kind of like a checklist, and if it's something I forgot to bring up, we can actually discuss it and whatnot.*"
	001–011/WHO FC II: "*It would be helpful for me to make sure I don't leave off anything or forget anything that I intended to talk to the doctor about. I think it's easier for the doctors because you've got your questions already prepared that you want answered. Saves time. And if you actually went in with these questions in your hand, it gives you a place to write down answers.*"
Expectations for scores	001–004/WHO FC II: "*Well, I would expect the doctor to keep record of these questionnaires from appointment to appointment and see any trends and make any recommendations according to how it's filled out. And maybe even make recommendations that day if they can see areas where you're really struggling.*"
	001–009/WHO FC II: "*I would expect him to assess if I need to start any new medications, and I would expect them to compare that with my last visit to see my progress. It would be another tool.*"
	001–006/WHO FC III: "*I would expect him to evaluate the change, the trend, because that's to me important. It's the way things move. Then make a decision on changing medication, increasing medication, therapies or whatever else to be given to effect the change.*"
Usefulness of reviewing scores with doctor	001–001/WHO FC II: "*I think it would be useful. I think it would be good to talk about the different symptoms and the symptoms that I am encountering on a weekly or daily basis.*"
	001–008/WHO FC III: "*This would be a wonderful asset to any pulmonary or cardio doctor anywhere.…they should send this to every pulmonary and cardio doctor.*"
	001–006/WHO FC III: "*Very [useful]. Yes, I think it would help us to communicate with each other, to give each other an idea of where we actually stand and what position we are in.*"

Abbreviations: *HCP* Healthcare provider, *SYMPACT-CP* Symptoms and Impact for Use in Clinical Practice, *WHO FC* World Health Organization Functional Classification

with HCPs by patients with PAH included shortness of breath, swelling, light-headedness, and heart palpitations.

Besides the SYMPACT-CP, another version of the PAH-SYMPACT has been previously described, in which symptoms and impacts are both reported on day 7 with a recall period of 24 h for symptoms and one week for impacts [15]. This version is based on a retrospective analysis of data from the phase 3 SYMPHONY trial of PAH, a study designed to validate the PAH-SYMPACT. That trial found mostly high or very high correlations between weekly average and individual day symptom scores, appearing to suggest that the 1-day/24-h recall version is feasible and appropriate for routine use in clinical practice [15]. However, patients in SYMPHONY had relatively stable disease [15], and correlations may be weaker for heterogenous clinical practice patients with greater fluctuations in symptoms. Further, the 7-day recall version presented here (SYMPACT-CP) is better suited for use in clinical practice, where information about symptoms is collected less frequently. In this line, the SYMPACT-CP allows HCPs to learn about symptoms irrespective of whether they occur daily, while symptoms that do not always occur daily (such as chest pain or heart palpitations) may be missed by the 1-day/24-h recall version of the PAH-SYMPACT. As such, the SYMPACT-CP may help capture a more comprehensive view of the symptom burden. Indeed, recall periods equivalent to the 7-day period (for example, "past week") are used in other PROs such as the Quality of Life Questionnaire-Core 30 [19, 20].

A potential limitation of this study was that it was restricted to a small number of patients, although the demographic and clinical characteristics of the sample are generally representative of the wider PAH population [3, 21, 22] and consistent with previous studies [10, 11, 13]. Further, as the study was conducted in

the US, our results may not be representative of other geographic regions. However, while disparities in PAH presentation have been detected between communities [23], there is currently no evidence that members of different communities differ in their responses to PROs like the SYMPACT-CP. Notably, the PAH-SYMPACT was psychometrically validated in a sample including Black/African-American and Asian patients with PAH [10] and has been used clinically in different world regions [11, 24, 25]. Although the present analysis did not include a psychometric evaluation of the SYMPACT-CP, we acknowledge the importance of conducting such analysis and plan to address this in future research. Finally, due to the one-off nature of interviews in this study, although participants' responses suggest that symptom severity may vary over time (supporting use of a 7-day recall period for clinical trials and regulatory purposes), any variations could not be directly assessed.

PROs like the SYMPACT-CP may improve the detection of issues experienced by patients, allow better monitoring of their experiences, and inform discussions between them and their HCPs [26]. In previous research, patients with PAH supported using questionnaires in clinical visits and appreciated the opportunity to discuss with their HCPs how their disease affected their lives [27]. Overall, the findings of this study support that the SYMPACT-CP has the potential to facilitate more structured conversations around patients' experiences and wellbeing during medical appointments, ensuring that any symptoms experienced are captured, and that it could be used to track symptom progression or inform treatment management. Enabling easier communication between patients and HCPs promotes a patient-centered approach to clinical practice. While clinician-reported outcomes are useful for assessing visible signs/behaviours that benefit from clinical judgment, PRO reports are key for symptoms best assessed by patients themselves [8]. Using PROs such as the SYMPACT-CP could help bridge the reported gap between HCP and patient assessment [28]. However, integrating PROs into clinical practice requires addressing various practical and methodological issues that can limit their application [29]. Therefore, future work should focus on how to implement the SYMPACT-CP in clinical practice to maximize its adoption and its relevance to routine management of PAH. Other pulmonary hypertension–specific PROs have been shown to provide prognostic information [30], so further investigation could assess whether incorporation of the SYMPACT-CP in clinical practice could improve monitoring of patients' clinical status. Finally, use of the SYMPACT-CP in other forms of pulmonary hypertension in which the PAH-SYMPACT has been studied, like chronic thromboembolic pulmonary hypertension [31], should also be explored.

Conclusion

The current study demonstrates that the SYMPACT-CP is valid for use in clinical practice to assess symptoms and impacts of PAH. With its consistent 7-day recall period for both symptoms and impacts, it should help patients better recall symptoms and their variability and bring them to the attention of their HCPs, which may improve symptom monitoring and disease management.

Abbreviations

HCP	Healthcare provider
PAH	Pulmonary arterial hypertension
PAH-SYMPACT	Pulmonary Arterial Hypertension-Symptoms and Impact
SYMPACT-CP	Pulmonary Arterial Hypertension-Symptoms and Impact for Clinical Practice

Supplementary Information

The online version contains supplementary material available at https://doi.org/10.1186/s12890-025-03681-2.

Additional file 1: Table S1 Interviewer qualifications. Table S2 Abbreviated interview guide. Table S3 Participant responses to the shortness of breath item. Table S4 Participant responses to the fatigue item. Table S5 Participant responses to the lack of energy item. Table S6 Participant responses to the swelling in ankles or legs item. Table S7 Participant responses to the swelling in stomach area item. Table S8 Participant responses to the cough item. Table S9 Participant responses to the heart palpitations (heart fluttering) item. Table S10 Participant responses to the rapid heartbeat item. Table S11 Participant responses to the chest pain item. Table S12 Participant responses to the chest pain item. Table S13 Participant responses to the lightheadedness item.

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Authors' contributions

SD, AB, and BB conceived of the study. SD, LK, and AK contributed to data analysis. All authors participated in study design, data interpretation, manuscript drafting, and critical revision, and final approval of the version to be submitted. All authors had full access to the study data and agree to be accountable for all aspects of the work, in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved.

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Data availability

The datasets used and/or analysed during the current study are available from the corresponding author on reasonable request. The qualitative data in this study (transcripts and interview notes) will not be made publicly available as they contain information that could compromise research participant consent.

Declarations

Ethics approval and consent to participate

This study was performed in accordance with the provisions of the Declaration of Helsinki, International Conference on Harmonization Guideline for

Good Clinical Practice, Good Pharmacoepidemiology Practice, and the applicable legislation on Non-Interventional Studies and/or Observational Studies. The study protocol and consent forms were approved by the Western-Copernicus Group institutional review board (no. 20225418). Informed consent was obtained from all subjects and/or their legal guardian(s).

Consent for publication
Not applicable.

Competing interests
AS and LK are employees of Evidera and received payment from Janssen Pharmaceuticals, Inc. for conducting the study. SD is an employee of Janssen Pharmaceuticals, Inc. AB and BB are employees of Actelion Pharmaceuticals Ltd., a Janssen Pharmaceutical Company of Johnson & Johnson.

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