Impact of psychological factors on the health-related quality of life of patients treated for pulmonary arterial hypertension

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\textbf{ABSTRACT}

\textbf{Objective:} Pulmonary arterial hypertension (PAH) is a rare and life-threatening disease well-marked by under diagnosis, delayed diagnosis and atypical treatments. Few data are available on the quality of life (QoL) and psychosocial characteristics of patients with PAH. Our aim is to describe the impact of psychological factors on the health-related quality of life (HRQoL) of treated PAH patients in a cross-sectional study.

\textbf{Methods:} Consecutive patients presenting at our Competency Centre for PAH were recruited. The aetiology, New York Heart Association (NYHA) stage, haemodynamics, 6-min walk distance (6MWD), delta SPO\textsubscript{2} (Pulse oximeter oxygen saturation; baseline lowest value during 6-min walk test (6MWT), current treatments and psychological history were recorded. HRQoL, anxiety, depression and coping strategies were explored using self-administered questionnaires (SF-36, HADS, STAI-Y, CHIP and WCC).

\textbf{Results:} A total of 55 patients were included. The HRQoL of PAH patients was poor with altered results on several scales. Anxiety and depression were high and coping was focused on medical information strategies. Multivariate analysis indicated a positive relationship between 6MWD and the Physical Composite Score for QoL (\(p = 0.004\)), as well as a negative relationship between delta SPO\textsubscript{2} and the Mental Composite Score (\(p = 0.02\)), irrespective of other known prognostic factors (such as haemodynamics at right heart catheterization). Depression and Trait-Anxiety were associated with a lower physical (\(p = 0.001\)) and mental (\(p < 0.001\)) QoL, respectively.

\textbf{Conclusions:} Psychological factors impact the HRQoL of treated patients. A longitudinal and qualitative study should refine these results.

**Trial Registration:** Clinical trial N\textsuperscript{o}: NCT01380054.

\bibliography{references}

1. \textbf{Introduction}

Pulmonary arterial hypertension (PAH) is a rare disease characterized by progressive elevation of pulmonary arterial pressure leading to right-side heart failure and was previously thought to occur primarily among women [1]. In the beginning of PAH, symptoms remain vague (fatigue, shortness of breath on exertion, exercise limitations) and patients may consult several doctors before being diagnosed. In 2006, there were approximately 1700 PAH patients in France and between 15 and 50 cases per million individuals worldwide [2]. Thirty years ago, the life-expectancy of a patient with PAH was only 3 years after diagnosis. Today, treatments have been developed and the physical/cardiovascular effects of PAH are well documented. Though overall prognosis has improved [3], mortality remains high. At all stages of PAH, patients are faced with a serious medical and psychosocial situation that can have potentially life-altering consequences (interruption of professional activity, sedentary life-style, high risk of morbidity and mortality during pregnancy). Most researchers insist on the need for longitudinal studies [4] and many publications start with the words: “PAH is a devastating or debilitating disease...” [4–7].

In the literature, the terms “health status”, “health-related quality of life” and “quality of life” are used interchangeably [8]. For the purposes of this paper, we retain a definition of HRQoL derived from the WHO definition of QoL [9]: HRQoL is defined as an individual's perception...
concerning his/her own health, integrating impacts related to diseases or treatments on his/her QoL [10]. Due to lack of consensus, many HRQoL questionnaires actually measure self-perceived health status [11].

Current literature on the psychological characteristics and HRQoL of PAH patients is composed of small studies, often targeting specific populations or patient association members [12–14]. This can be linked to difficulties in recruiting patients who have chronic disease, but with a short life-expectancy, resulting in many studies that are cross-sectional and of short duration [15]. In addition, the fact that women are usually overrepresented in PAH studies (from 81 to 88% of cases) [4, 6, 16–19] may bias results concerning emotional responses focused on anxiety, depression or QoL [20]. Depression is nearly always investigated using self-questionnaires sent to the patient’s home, whereas these symptoms merit a face to face clinical evaluation [21–23]. Finally, with a few rare exceptions [12, 17], most such studies focussing on psychological disorders involve no or few psychologists and/or researchers in psychology. In incident patients, HRQoL is a prognostic marker in PAH [24] and today, international guidelines recommend improving PAH-related QoL and providing psychological management [1]. It is therefore time to focus on studies involving multidisciplinary teams, including professionals in psychology, as well as more representative populations.

The objectives of the PAH and Psychological factors (HyPsy) study were to investigate the impact of psychological factors on HRQoL, the association between HRQoL and the evolution of PAH, as well as the evolution of HRQoL. In this report, we describe the cross-sectional analysis of HRQoL in the HyPsy study population and the psychological characteristics of the patients at the time of study inclusion.

2. Methods

2.1. Patients and study design

The Montpellier Hospital became the Regional Competence Centre for PAH in Languedoc-Roussillon (France) in 2008. Following this, patients rapidly requested socio-psychological help. Taking into account the scarcity of data, at the end of a meeting involving the referent pulmonologist for PAH, a psychologist and the French Association of PAH patients, the decision to implement a prospective study was taken, beginning in May 2011.

Consecutive patients with idiopathic, post-embolic, familial PAH or PAH associated with various diseases were recruited (Groups I and IV of the last ESC/ERS classification [25]). The criteria for the definition of the disease (mean pulmonary arterial pressure (mPAP) > 25 mmHg, pulmonary capillary wedge pressure (PCwp) < 15 mmHg, right ventricular pressure (RVP) > 3 wood units, presence of ventilation-perfusion (V/Q) scan mismatches for group IV) were derived from the recommendations of the 5th World Congress on PAH (Nice, France, March 2013) [26]. The inclusion criteria were: age 18–80 years; prevalent or incident cases (newly diagnosed, stable for ≥ 3 months); specific NYHA functional class severity I to IV; not operable; not receiving psychological care in the Competency Centre. The exclusion criteria included: low cardiac output (cardiac index < 2 L/min/m²); pre-mortem state; and cognitive impairments.

The anticipated duration of participation was 48 months. The patients were seen every 3 months to assess their clinical and psychological state. Ethics committee approval for the study was granted by the Committee for the Protection of Persons, South-Mediterranean III, (reference number: 2011.04.01). All patients gave their written informed consent to participate in the study.

2.2. Data collection

The initial medical assessment was carried out by the clinician responsible for the study. The medical data collected included: NYHA functional class; comorbidities (psychotropic medications); specific treatments for PAH; long term oxygen therapy, 6MWD (at rest and minimal pulse oximeter oxygen saturation (SPO2), distance and Borg dyspnoea visual scale score); echocardiography; and haemodynamic parameters recorded at right heart catheterization (RHC). A psychosocio-demographic questionnaire was completed by all patients. Given the current lack of French validated questionnaires for the PAH population, we chose general-population tools (which additionally enabled comparison with other, better-known, serious diseases), validated in French, and which previously demonstrated published utility in PAH populations [16, 17, 21]. All questionnaires were completed in the presence of the project psychologist.

The Medical Outcomes Study 36-item Short Form Health Survey (SF-36), version 1.0, is a generic HRQoL scale which explores physical, emotional and social health status [27] and is well-validated in French [28]. It evaluates eight dimensions of health: (i) physical functioning; (ii) role limitations due to physical health problems; (iii) bodily pain; (iv) general health; (v) vitality; (vi) social functioning; (vii) role limitations due to emotional problems; and (viii) mental health. The physical composite score (PCS) and mental composite score (MCS), summarize these eight dimensions. The lower the score, the poorer the HRQoL.

Anxiety and depression were studied with the Hospital Anxiety and Depression Scale (HADS) [29] and the State-Trait Anxiety Inventory (STAI-Y) [30], both validated in French [31–34]. The HADS detects anxiety and/or depression, evaluates their severity and avoids confusion with somatic illnesses (non-cases: 0–7; possible cases: 8–10; probable cases: 11–21). The global score was also taken into account: no anxiety-depressive disorders: 0–14; presence of anxiety-depressive disorders: 15–42 [35]. The STAI-Y evaluates anxiety and differentiates trait (TA) from state anxiety (SA) (very high anxiety > 65, high = 56–65, average = 46–55, low = 36–45, very low ≤ 35). TA can be defined as personality disposition, a relatively stable tendency to feel stress. SA can be defined as fear induced temporarily by situations perceived as dangerous.

Coping refers to the thoughts and actions we use to deal with a situation in order to master or tolerate stress. Coping strategies were studied with the Ways of Coping Check List (WCC), which is linked to a stressful event [36] and the Coping with Health Injuries and Problems (CHIP) scale, specific to health-related problems [37]. Both were validated in French [38, 39]. The CHIP scale was constructed for patients with cancer and revised for patients suffering from other somatic diseases. Normative data for study comparisons are provided in the manual [40]. It includes four sub-scales: ‘Distraction’ defined as: attempts to think of more agreeable things; ‘Instrumental’: strategy linked to the search for medical information; ‘Emotional’: focus on emotional aspects linked to the state of health (anger, frustration, worry, etc.); ‘Palliative’: alleviates the unpleasant aspects of the situation (taking care of oneself, sleeping, etc.). The WCC identifies, from a stressful situation not linked to the disease (divorce, moving, conflict, etc.), strategies which have been used to confront the situation. It includes three sub-scales for coping (problem-focused, emotion-focused, search for social support).

2.3. Statistical analysis

Quantitative variables derived from the descriptive analysis are expressed as means ± standard deviation and qualitative variables as numbers and percentages. Due to non-normal distributions and a relatively small number of patients in our cohort, we decided to dichotomise the PCS and MCS scores, in order to obtain greater statistical power and a clearer clinical interpretation. Given that pertinent SF-36 cut offs do not currently exist, we chose a statistic, reproducible option: the cut-offs were defined as the PCS and MCS medians (36.92 and 43.46, respectively). Two logistic regression models were then established to model the relationships between psychological and clinical
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