ORIGINAL ARTICLE IN HEALTH PSYCHOLOGY

Psychological counselling interventions to improve perceived quality of life and counter anxiety and depression in pulmonary-arterial-hypertension patients: A clinical trial

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Abstract

Introduction: Pulmonary Arterial Hypertension (PAH) is a rare and progressive disease, frequently associated with a worsening of perceived quality of life as well as anxiety and
depression symptomatology. Psychological counselling helps the patient understand the diagnosis and prevent the onset of psychopathologies. This study evaluates the effect of counselling sessions on anxiety and depression as well as the impact on self-reported quality of life in patients with PAH.

**Methods:** Patients with a diagnosis of PAH were recruited at the Monaldi Hospital (Naples). An EQ-5D 3L questionnaire was administered to all patients at baseline (pre-session), three months (post-session) after the last session to patients who received psychological counselling (experimental group, EG) and after the first questionnaire to patients who did not (control group, CG). The EQ-5D index and EQ-VAS score were analysed in both groups.

**Results:** A sample of 50 patients with a PAH diagnosis was evaluated; among them 6% had mild PAH, 66% moderate PAH, and 28% severe PAH. The majority (53%) did not receive psychological counselling. All patients showed no significant difference in EQ-5D index \((P > 0.05)\), EQ-VAS score \((P > 0.05)\), and the anxiety/depression dimension \((P > 0.05)\) at baseline. However, between pre- and post-session evaluations, the analysis showed a significant change in the EQ-VAS score \((P = 0.00)\) and the anxiety/depression dimension \((P = 0.02)\) in the EG. In the CG, there was a similar change in the anxiety/depression dimension \((P = 0.00)\) but not in the EQ-VAS score \((P = 0.05)\) in CG. The z-test revealed significant intergroup relations, showing that the EG had a 37% increase in perceived quality of life and a 9% reduction in anxiety and depression, while a 12% reduction was observed for the CG’s perceived quality of life and a 44% increase in anxiety and depression.
Discussion and Conclusions: This study showed that patients with PAH who received psychological support improved their health-related quality of life by reducing anxiety and depression symptomatology. Our findings highlight the impact of psychological support in the treatment of patients with PAH.

KEY WORDS: anxiety; counselling psychology; depression; EQ-VAS; EQ-5D; pulmonary arterial hypertension; quality of life.

Riassunto

Introduzione: L'ipertensione arteriosa polmonare (IAP) è una malattia rara e progressiva, frequentemente associata al peggioramento della qualità della vita percepita, nonché a sintomi di ansia e depressione. Il counseling psicologico aiuta i pazienti a comprendere la diagnosi prevenendo l'insorgenza di psicopatologie. Questo studio ha l'obiettivo di valutare l'effetto di sessioni di counseling sull’ansia, la depressione e la percezione della qualità della vita in pazienti con IAP.

Metodi: I pazienti con diagnosi IAP sono stati reclutati all’Ospedale Monaldi di Napoli. Il questionario EQ-5D 3L è stato somministrato a tutti i partecipanti al primo incontro di counselling (pre-session) e a distanza di tre mesi (post-session) in due gruppi: quelli che hanno ricevuto il percorso di counselling (gruppo sperimentale) e quelli che hanno effettuato un solo incontro (gruppo di controllo). L'indice EQ-5D e il punteggio EQ-VAS sono stati analizzati in entrambi i gruppi.

Risultati: È stato valutato un campione di 50 pazienti con diagnosi di PAH; il 6% presentava una forma lieve di IAP, il 66% una forma moderata ed il 28% una grave. La maggioranza di loro
(53%) non ha ricevuto il counselling psicologico. Tutti i pazienti non hanno mostrato differenze significative nelle scale EQ-5D ($P > 0.05$), EQ-VAS ($P > 0.05$) e nella dimensione ansia/depressione ($P > 0.05$) nella fase di pre sessione. Tuttavia, l’analisi tra pre e post-sessione ha mostrato un cambiamento significativo nel punteggio EQ-VAS ($P = 0.00$) e nella dimensione ansia/depressione ($P = 0.02$) nell'EG. Nel CG, vi è stato un cambiamento simile nella dimensione ansia/depressione ($P = 0.00$) ma non nel punteggio EQ-VAS ($P = 0.05$) in CG. Lo z-test ha rivelato significative relazioni intergruppi, mostrando con l'EG un aumento del 37% nella qualità di vita percepita e una riduzione del 9% di ansia e depressione, mentre è stata osservata una riduzione del 12% nella qualità di vita percepita al CG e un 44% di aumento di ansia e depressione.

**Discussione e Conclusioni:** Questo studio ha dimostrato che i pazienti con PAH che hanno ricevuto supporto psicologico hanno migliorato la loro qualità di vita correlata alla salute riducendo la sintomatologia dell'ansia e della depressione. I nostri risultati evidenziano l'impatto che il supporto psicologico può avere nel trattamento dei pazienti con PAH.

**TAKE-HOME MESSAGE.** The psychological counselling can improve both perceived quality of life and the anxiety and depression management in patients with PAH.

**Competing interests:** none declared
INTRODUCTION

Pulmonary arterial hypertension (PAH) is a rare and progressive disease [1] characterized by a pathological alteration to the pulmonary arterioles (diameter less than 500 µm), leading to a progressive increase of pulmonary vascular resistance and consequently to right ventricular failure and ultimately death [2]. The prevalence of PAH is approximately 50 per 1,000,000 people [3, 4]. Therefore, we can estimate the existence of approximately 3,000 PAH patients in Italy [5].

Early diagnosis of PAH is difficult because of the delay between the onset of symptoms and diagnosis [6, 7]. The delayed diagnosis is mainly attributable to the presence of non-specific symptoms such as physical weakness (asthenia), thoracic pain (angina), oedema, sudden loss of consciousness (syncope), and progressive dyspnoea (shortness of breath), which reflect cardiac insufficiency [1].

In the past, PAH patients’ survival was strongly dependent on the disease’s severity and the limited PAH-specific treatments [8, 9]. Moreover, despite the increased availability of PAH-specific treatments that improve patients’ survival PAH is still a progressive and chronic disease with high mortality [1].
Life with a PAH diagnosis, as with chronic diseases in general, often includes navigating complex treatments, the prevention of harmful situations, regular contact with the healthcare system, as well as social, identity-related, and emotional concerns. All these factors considerably reduce the patient’s quality of life [2, 10, 11]. Therefore, in the treatment of PAH, all available resources should be considered in order to create a system of care characterized by strong relationships, dialogue, confidence, and shared meaning process [12, 13].

Frequently, patients are treated as passive participants, but healthcare professionals would benefit from adopting an approach focused on the active role of the patient in the therapeutic process in order to avoid therapeutic non-compliance. Even if simply improving patients’ survival is chief among the treatment goals of a chronic and potentially fatal disease such as PAH, the importance of patients’ quality of life should not be underestimated [14]. Social and emotional aspects are an important part of the patient–disease relation, especially in PAH [15].

PAH is often associated with psychopathological issues due to the management of different stressful factors such as an unclear diagnosis, the high emotional cost of treatments, consequent unemployment, or premature retirement [16]. All of these factors have an important psychological impact on the perception of the disease, in areas such as the diagnosis, life expectancy, and the consequential physical limitations [17]. Moreover, the onset of anxiety and depressive disorders seriously impacts the perception of the disease and life, decreasing quality of life [18–20].

A multidisciplinary approach should be considered to ensure that the patient understands and takes into account physicians’ advice about therapies, diet, physical exercise, and psychological
support [15]. In this view, psychological counselling should be a support in the care of patients affected by incurable diseases with quality of life impairments such as PAH. Psychological counselling aims to contrast the onset of psychopathologies often associated with a decrease in perceived quality of life and a consequent planning-ability block [21–23].

The purpose of the present study was to evaluate the impact of psychological counselling on anxiety and depressive states and on the health-related quality of life (HRQoL) in patients with a diagnosis of PAH.

METHODS

Study design, procedure, participants and sampling

The present study was designed to evaluate the impact of the psychological counselling without putting the patient under additional stress. For this study, the EuroQol 5-dimensional (EQ-5D) questionnaire was used, integrated with socio-demographic questions (i.e., gender, age, employment status, educational qualification, marital status) [24]. Participants with a diagnosis of PAH, treated and followed at the Centre for the Diagnosis and Treatment of Pulmonary Hypertension (Monaldi Hospital, Naples) were enrolled between February 2019 and April 2020. All patients were asked to participate in the study by a psychologist with expertise in psychological counselling during routine visits to the centre. Patients who died during the study and patients unwilling to provide consent were excluded.

To evaluate the impact of the psychological counselling in patients with PAH, participants were asked to complete the EQ-5D questionnaire after obtaining written informed consent (pre-session). The inclusion criteria were: age between 14 and 69 years and absence of severe physical
The exclusion criteria were: age over 69 or under 14 years or presence of severe physical comorbidity. The sample obtained was divided into two randomized groups: patients who did not participate in counselling (control group, CG) or who participated to only one counselling session and those (experimental group, EG), who received four hours sessions of psychological counselling. Both groups were asked to complete the second, post-session, EQ-5D questionnaire three months after the first for the CG, and three months after the last counselling session for the EG. The EQ-5D questionnaire was administered by a psychologist specialized in systemic psychotherapy.

The psychological counselling consisted of four sessions every two weeks. Each session focused on coping with anxiety and depressive states as well as supporting the patient in facing the limits imposed by the disease [25]. The purpose of the psychological counselling was to contain the onset of anxiety and depressive symptomatology and to improve or stabilize their perceived quality of life.

**Instruments and measures**

The EQ-5D is a standardized, self-administered questionnaire to measure health-related quality of life (HRQoL) [26]. It is widely used in clinical trials due to its ease of understanding for patients [27]. The EQ-5D is composed of two different sections. The first part consists of five dimensions (mobility, self-care, usual activities, pain/discomfort, anxiety/depression) related to the patient’s general health state. In the three-level (3L) version (EQ-5D 3L), subjects rate their current health status using three response options (no problems, some/moderate problems, severe problems/unable to) for each dimension. The results can be combined in a set of five-digit
numbers describing an individual HRQoL. A total of 243 possible health states can be defined, and each can be converted into a single index (EQ-5D index), where the highest possible value (1.00) signifies the best possible health state [21].

The second part consists of a visual-analogue scale (EQ-VAS) on which patients rate their self-perceived health state with a score from 100 (‘the best imaginable health state’) to 0 (‘the worst imaginable health state’) [21].

In this study, PAH severity was evaluated with a REVEAL 2.0 risk score. This score is one of the tools used as guidance in selecting the best therapeutic option for patients [8]. The REVEAL 2.0 risk score analysed different clinical variables (i.e., mean arterial pressure, pulmonary vascular resistance, systolic blood pressure, heart rate, WHO functional class, exercise capacity, pulmonary functionality, BNP level, renal insufficiency) that allow the stratification of the patient into three categories of PAH (mild, moderate and severe) [9].

**Ethical aspects**

This study was approved by the Ethics Committee of the Ospedale dei Colli Monaldi (Naples), with clinical trial number AOC/0021333/2020 and an iPHNET (Italian Pulmonary Hypertension NETwork) board of director. Patients voluntarily participated in this study. The study was conducted according to the Declaration of Helsinki. Prior to any experimental data collection, written and verbal informed consent was obtained from each participant following a verbal description of all experimental details. Patient confidentiality was guaranteed. All psychological counselling sessions were conducted with the Ethical Framework for Good Practice in Counselling and Psychotherapy [26].
Data analysis

Descriptive statistics were used to estimate socio-demographic variables, the health state (EQ-5D index), and self-reported health status for the whole sample as well as for the different subgroups. Statistical comparisons included a Student's t-test, z-test, and one-way ANOVA [28–30] for the EQ-5D index, EQ-VAS score, and anxiety/depression dimension. Results were given as mean ± standard deviation (SD) or number. A P-value < 0.05 was considered significant. All statistical analyses were performed with SPSS v.20 [31].

RESULTS

Socio-demographic characteristics

A sample of 50 patients with a PAH diagnosis was evaluated (average age 53.48 ± 16.62 years). The majority was female (72%). Among them 3 (6%) had mild, 33 moderate (66%), and 14 severe (28%) PAH. The majority of patients (53%) did not participate in psychological counselling, completing only the second EQ-5D 3L questionnaire three months after the first, pre-session, questionnaire. Forty-eight percent of patients did not participate in psychological counselling after the completion of the first, pre-session, EQ-5D 3L questionnaire.

Statistical analysis

To understand the relationship between patients’ health state and self-reported health state, the pre-session EQ-5D index and EQ-VAS score were compared in both groups. A bivariate statistical analysis showed a significant difference between groups ($r = 0.62$, $P < 0.001$),
indicating that the score for self-reported health state increases as perceived quality of life increases.

To evaluate the patients’ basal psychological state, the EQ-5D index and EQ-VAS score were evaluated in both groups for the pre- and post-session questionnaire results. Additionally, the anxiety/depression-dimension score was investigated to understand the impact of psychological intervention in patients’ symptomatology.

A Student t-test showed no difference in EQ-5D index \((P > 0.05)\), EQ-VAS score \((P > 0.05)\), and particularly in anxiety/depression-dimension scores \((P > 0.05)\) between groups at baseline (pre-session), displaying uniformity in patients’ psychological perspective (Table 1).

Descriptive analysis showed that self-perceived health state tends to be low, in particular in patients with severe PAH (mean 49.13 in patients who obtained a 2.52-point mean in PAH severity) (Table 1). Specifically, in the CG, the EQ-VAS score was higher \((55.18 \pm 18.54)\), although there was no significant difference \((P = 0.37)\), such as in the EQ-5D index \((P = 0.94)\) and the anxiety/depression-dimension score \((P = 0.26)\) (Table 1).

**Table 1.** Mean and Student t-test for EQ-5D index, anxiety/depression dimension and PAH severity.*

<table>
<thead>
<tr>
<th></th>
<th>Experimental Group ((n = 24))</th>
<th>Control Group ((n = 26))</th>
<th>Sample ((n = 50))</th>
<th>95% CI</th>
<th>(P)</th>
</tr>
</thead>
<tbody>
<tr>
<td>EQ-5D index</td>
<td>0.47 (0.32)</td>
<td>0.48 (0.31)</td>
<td>0.49 (0.32)</td>
<td>-0.13, 0.23</td>
<td>0.94</td>
</tr>
<tr>
<td>EQ-VAS score</td>
<td>49.13 (29.77)</td>
<td>55.18 (18.54)</td>
<td>52.4 (29.77)</td>
<td>-4.67, 28.83</td>
<td>0.37</td>
</tr>
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</table>
Regarding the severity of PAH, there was a statistical difference between groups \((P = 0.00)\), indicating that patients who did not participate in psychological counselling showed a better clinical outcome compared to the patients who did (Table 1). From the psychological point of view, the groups showed uniformity in perceived quality of life and anxiety/depression-dimension score. Table 2 shows data from EQ-5D index and anxiety/depression dimension in the EG and CG, both pre- and post-session between and within groups. A Student t-test of the anxiety/depression-dimension score pre- and post-session showed a significant difference in the EG \((P = 0.02)\), with a reduction of symptomatology \((MD = -0.29)\). For the EQ-VAS score, statistical analysis showed an increase in scores between pre- and post-session results \((MD = +21.3)\) and a statistical significant difference \((P = 0.00)\). In the CG, statistical analysis showed no difference between pre- and post-session EQ-VAS score \((P = 0.05)\) and a reduction in scores \((MD = -7.44)\). For the anxiety/depression-dimension scores, results showed a significant difference between pre- and post-session results \((P = 0.00)\) and an increase in scores \((MD = +0.32)\). Moreover, the between-group-comparison results showed a significant difference for the EQ-VAS score \((P = 0.03)\), but not in the anxiety/depression-dimension score \((P = 0.09)\) (Table 2).
Table 2. Student t-test between and within groups for self-perceived health state and anxiety/depression dimension.*

<table>
<thead>
<tr>
<th></th>
<th>Pre-session</th>
<th>Post-session</th>
<th>MD</th>
<th>CI</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td><strong>EG (n = 24)</strong></td>
<td></td>
<td></td>
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<td></td>
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<tr>
<td>EQ-VAS score</td>
<td>49.13 (29.77)</td>
<td>70.43 (17.70)</td>
<td>+21.3</td>
<td>13.97, 28.59</td>
<td>0.00</td>
</tr>
<tr>
<td>Anx/Dep</td>
<td>2.29 (0.79)</td>
<td>2 (0.60)</td>
<td>-0.29</td>
<td>-0.53, -0.04</td>
<td>0.02</td>
</tr>
<tr>
<td><strong>CG (n = 26)</strong></td>
<td></td>
<td></td>
<td></td>
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<td></td>
</tr>
<tr>
<td>EQ-VAS score</td>
<td>55.18 (18.54)</td>
<td>47.74 (19.26)</td>
<td>-7.44</td>
<td>-21.97, 0.07</td>
<td>0.05</td>
</tr>
<tr>
<td>Anx/Dep</td>
<td>2.27 (0.83)</td>
<td>2.59 (0.64)</td>
<td>+0.32</td>
<td>0.08, 0.60</td>
<td>0.00</td>
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<tr>
<td><strong>EG-CG (n = 50)</strong></td>
<td></td>
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<td></td>
<td></td>
</tr>
<tr>
<td>EQ-VAS score</td>
<td>52.4 (29.77)</td>
<td>58.18 (21.63)</td>
<td>+5.78</td>
<td>13.06, 39.31</td>
<td>0.03</td>
</tr>
<tr>
<td>Anx/Dep</td>
<td>2.28 (0.79)</td>
<td>2.32 (0.68)</td>
<td>+0.04</td>
<td>-0.96, -0.26</td>
<td>0.09</td>
</tr>
</tbody>
</table>

Note: Anx/Dep = anxiety/depression dimension; CI = confidential interval; MD = mean difference *Data are shown as mean (±SD) or number

Thus, to better understand the relationship between means, results were analysed by a one-way ANOVA considering the factor of the anxiety/depression dimension. The analysis showed a significant effect on anxiety/depression-dimension scores between groups \([F (1, 48) = 12.49, P = 0.00]\), revealing a reduction in anxiety and depression symptomatology in patients who participated in counselling sessions. On the other hand, analysing the results with z-test between groups to evaluate the quality of the impact of psychological counselling between the CG and EG, the analysis showed a significant difference for the EQ-5D index \((Z = 2.08, P > 0.05)\) and the anxiety/depression-dimension score \((Z = -3.43, P = 0.00)\), revealing that the psychological intervention improved perceived quality of life and anxiety and depression symptomatology.
The EG showed a 37% improvement in perceived quality of life (EQ-VAS) and a 9% decrease in anxiety/depression-dimension scores, while the CG showed a 12% decrease in perceived quality of life and a 44% increase in anxiety/depression-dimension score.

**DISCUSSION**

The goal of present study was to investigate the role of counselling sessions and psychological support for patients with PAH. To this end, the EQ-5D 3L questionnaire was administered before and after the psychological counselling. Different studies have shown that psychological support has a fundamental function in patient assessment, playing a role in the prevention and control of psychopathologies consequent to the diagnosis [19–21].

The results of the first evaluation indicate that the choice to access psychological support was affected by the gravity of the PAH diagnosis. Specifically, patients willing to participate in counselling sessions showed a worse clinical situation (i.e., severe PAH), even if all patients involved did not report worse HRQoL at baseline. These results are surprising because patients with a severe diagnosis showed a severe impairment in psychological-dimension scores and seem to consider the counselling sessions even when they ultimately reject them.

Furthermore, our findings indicate that the psychological support has the most benefit for patients who participated in all counselling sessions, improving their perceived quality of life and the management of anxiety and depression symptomatology. Moreover, their health state was not solely related to the absence of disease but also to physical, psychological, and social well-being [32].
There is evidence that positive perception of quality of life may be improved by undertaking psychological support [33–39], and psychopathological assessments [21, 40–45]. Our findings suggest that patients who did not participate in psychological support showed a worsening in perceived quality of life and, consequently, increased anxiety and depression symptomatology.

For this purpose, the counselling sessions focused on negotiation with the limits imposed by the disease, an important aspect that patients with PAH are compelled to confront. According to previous studies, the results of the present study have shown a difference between patients who participated in counselling sessions and patients who did not [46].

In particular, the results showed no difference between groups in anxiety/depression-dimension scores, perhaps due to the disease’s progression (i.e., increased physical limitations due to progression of the PAH leading to anxiety and depressive episodes) or to the small sample size. Patients who participated in psychological counselling showed an improvement in anxiety and depression symptomatology compared to patients who were unwilling to participate.

Different studies have shown that psychological support for subjects with chronic and severe diseases leads to a better life perspective in terms of self-reported quality of life [47–49].

Our findings show that subjects who participated in counselling sessions had a better perceived quality of life and, at the same time, more tools for managing the anxiety and depression symptomatology related to their clinical condition.

From the perspective of social and holistic medicine, psychological support may benefit the patient in therapeutic adhesion, acting on mechanisms of defence following a diagnosis that leads to physical and psychological deterioration.
**Study limitations and further research**

Limitations of the present study are that the EQ-5D questionnaire is a generic tool employed to measure and evaluate anxiety and depression level and some personality traits. In addition, the study was carried out at a single clinical site. In the future, these aspects should be considered in order to conduct a more complete evaluation. Further studies, particularly multicentred ones, are needed to validate the findings of this study and to better evaluate anxiety and depression levels with specific measurements that take into account the patients’ physical and emotional limits, providing medical staff as well as patients with tools and strategies to cope with the disease.

**CONCLUSION**

The present study has shown the impact of psychological support and its role in the treatment of the patients with a PAH diagnosis according to the ESC/ERS guidelines [50]. Psychological counselling is a useful tool to examine improvement in patients’ perceived quality of life and the consequent psychological benefits. The experience of a serious and degenerative disease like PAH may call into a question the existence of meaning and self-image, affecting perceived quality of life and personal well-being. After the diagnosis, the patient has to face a feeling of loss due to the anguish of death. All these aspects, if not taken into account, can negatively affect anxiety and depression states, especially if the risks related to the disease’s progression were considered [19, 51–55]. The opportunity to access a listening space can facilitate an emotional process that redefines the patient’s sense of their health state and helps them recover the competence to become an active protagonist, despite the limits imposed by a diagnosis of PAH [56, 57].
In term of treatment compliance, a full awareness of what the diagnosis involves in terms of psychological needs may hinder possible strategies of avoidance and denial [58], which could lead the patient to carry a difficult emotional load due to the treatments’ complexity.

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