Idiopathic Pulmonary Fibrosis: An EU Patient Perspective Survey

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Abstract: Idiopathic Pulmonary Fibrosis (IPF) is a chronic and progressive lung disease associated with a poor prognosis. A diagnosis of IPF dramatically impacts the life of patients. We conducted a qualitative survey to evaluate patient's insight and emotions during and after diagnosis. Patients with a physician-confirmed IPF diagnosis participated in an in-depth qualitative interview. Common projective techniques were used to reveal underlying feelings and attitudes, with the main objective to generate insights into patients' emotions and journey, including symptoms, referral patterns, diagnosis process, and follow-up. Additionally, some patients participated in an online *Insight Room* where they could discuss the disease and its impact on quality of life. Word use related to living with IPF was analyzed. Forty-five patients from five European countries were interviewed. Based on groupings into coping approach and age, four segments of emotions were identified: "combative", "dejected", "serene", and "stoic". Patients in each of the segments approached the disease in different ways. At the time of diagnosis, patients experienced a range of emotions: devastation, confusion, trust, and apprehension. After diagnosis, three successive emotional phases were identified: coming to terms (diagnosis), reactive coping (acceptance), and proactive coping (ownership of condition). The conversational co-word *Insight Room* analysis identified four areas of patient concern: the physical problem, family support, the medical world and hope for research. Supporting the emotional status of patients should become a more integral part of the management of IPF at diagnosis as is the standard for other terminal conditions, such as cancer.

Keywords: Depression, emotional support, idiopathic pulmonary fibrosis, patient feelings, patient perspective survey, social isolation.

1. INTRODUCTION

Idiopathic Pulmonary Fibrosis (IPF) is a chronic, progressive, fatal lung disease of unknown cause [1, 2], which is characterized by progressive breathing difficulty, cough, and basal crackles of both lungs, which can be heard *via* a stethoscope when breathing [1]. Presentation usually occurs in older (>50 years) men and women. Strongly associated risk factors for IPF include cigarette smoking and environmental/occupational exposures such as air pollution. Additional disorders experienced by patients with IPF can include obesity, emphysema, and abnormal pauses of breathing or low breathing rate during sleep. Patients with IPF have increased sleep disruption and poorer sleep quality. This can result in daytime fatigue, which negatively affects the emotional and physical functioning and well-being of patients [3, 5].

At the time of this survey, there was no available therapy for IPF for patients in the EU, although pirfenidone (Esbriet®, InterMune UK Ltd, London, UK) is now available, which was approved for treatment of mild-to-moderate IPF by the European Medicines Agency in 2011 [6]. Typical standards of care for patients now also includes long-term oxygen therapy and lung transplantation, should patient and disease criteria be met, as the disease worsens [1].

Patients with IPF typically demonstrate a decrease in lung function, which can hinder their normal daily physical activity [2]. Studies have shown that patients with IPF have impacted physical and social functioning, psychological symptoms, and levels of independence [7-9]. This in turn can lead to feelings of anxiety and depression and a reduced health-related quality of life (HRQOL) [7, 10]. Diagnosis of a chronic illness such as IPF may also impact heavily on caregivers, particularly as the disease progresses and worsens.

Although there have been studies examining the HRQOL of patients with IPF [3, 7, 8, 11], there have been few which specifically examine patient feelings and perceptions regarding IPF [5, 12].

A recently published study carried out by Schoenheit *et al*. [2] investigated the experiences of European patients with IPF regarding the diagnosis process and ongoing disease management. The aim of the study was to identify potential unmet patient needs and possible opportunities to improve quality of care [2].

This manuscript reports on secondary analyses carried out on these original published study data, with a focus on the emotions experienced by patients during different stages of the patient journey, from diagnosis to follow-up. This original study and subsequent analysis focused above all on listening to patients with IPF and capturing their thoughts and feelings regarding the pathology and their quality of life.

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2. METHODS

Secondary analyses were performed on data arising from a study in which interviews were conducted with patients with IPF in Europe [2].

The study involved in-depth, structured, at-home interviews with patients who had a physician-confirmed diagnosis of IPF. Referring physicians were asked to confirm that the patient had received a diagnosis of IPF, and the patient was also asked to confirm this at recruitment, using the screening questionnaire.

Potential responders were recruited with the assistance of IPF-treating physicians. In accordance with the European Pharmaceutical Marketing Research Association (EphMRA) guidelines, patient's informed consent to participate in the survey was obtained. Following this, potential respondents were contacted by an experienced recruiter, who explained the purpose and nature of the research, asked a series of screening questions, and established willingness or refusal to participate.

Interviews were carried out during June and July 2010 by a trained facilitator. Interviews were either one-to-one with the patient or included a caregiver. The duration of each interview was at least 1 hour. During the interview process, two projective interview techniques were used to encourage frank and open discussion: associative technique using images to express patient feelings and constructive technique using patient recall to discuss what was said at certain stages of the patient journey. Patients' emotions at distinct steps on the patient journey were discussed and recorded. These steps included symptoms, referral process, initial diagnosis, and after diagnosis.

Data obtained from the patient interviews including patient age, ability to cope with the disease and overall mindset were grouped and non-statistically analyzed. Patient segments based on age and mindset were identified using qualitative analysis methods involving data collation, identification and categorization of emergent themes, as well as development and validation of working hypothesis.

Additional analyses undertaken separately from the patient interviews involved creation of a pilot test online forum (*Insight Room*), which was established in the United Kingdom and ran for a period of 7 days between Wednesday 21 July 2010 and Tuesday 27 July 2010, with the aim being that conversations could be captured during a normal week for patients with IPF. Patients identified by their physicians were sent an invitation letter to join, which detailed the aims of the forum, the website address and dates it would run. Patients could enter the *Insight Room* 24 hours a day and discuss any aspect of their illness and patient journey with fellow patients. On the first day of the forum, the moderator showed participating patients the same 39 images that were used as part of the associative technique during the one-to-one interview process. These images were designed to cover a range of positive and negative emotions, physical sensations and symbolic representations. Images could be grouped into the following category types: nature/environment (n=16), people/emotions (n=16), animals (n=4), and objects/signs (n=3). Patients selected the five pictures which most accurately described their feelings regarding living with IPF. The moderator then asked them questions relating to these topics as a way to better understand their feelings and opinions, particularly in terms of quality of life.

Insight Room conversation transcripts were analyzed and the usage and frequency of terms were recorded for all conversations, and specifically those conversations referring to living with IPF. This metaphorical analysis was carried out with the T-LAB text analysis tool (www.tlab.it/en) which allows the identification and mapping of relationships and co-occurrences amongst single key-words, and hence highlight conversational trends or patterns. Mapping of word inter-relationships was followed by a qualitative analysis examining how the words were used, as well as their meaning within the context of all the other qualitative data gathered.

Ethical approval status: The patient interviews and *Insight Room* were conducted in accordance with The International Chamber of Commerce (ICC)/The European Society for Opinion and Market Research (ESOMAR) International Code on Market and Social Research [13] and thus did not require ethical committee approval. Data collected from both the interviews and *Insight Room* were made anonymous to maintain patient confidentiality. Informed consent was obtained from each patient, family member, and caregiver who participated in the interviews. The only data recorded *via* the *Insight Room* were the geographical location of each participant. No other demographic data were recorded.

3. RESULTS

3.1. Demographic and Medical History

Forty-five patients with IPF were interviewed from five European countries (Germany, France, Italy, Spain, and the United Kingdom) [2]. The median patient age was 67 years. Caregivers participated in 40% (n=18) of interviews. Seven patients (16%) had progressive disease, having been diagnosed with IPF since the year 2000. The majority of patients (n=27, 60%) received a diagnosis of IPF between 2006 and 2010. Although every patient journey was unique, two diagnostic paths were identified. The most common diagnostic path occurred *via* a protracted route (patient diagnosed any time between 1 and 12 years, n=26, 58%), which was characterized by repeated physician visits, dismissal of symptoms, and misdiagnoses including allergic asthma, pneumonia, chronic bronchitis or chronic obstructive pulmonary disease. The early diagnostic path whereby a patient was diagnosed within one year (n=19, 42%) was usually as a result of a well informed patient or physician.

Regarding the strongly associated risk factors for IPF, although 76% of patients confirmed they had smoked at one time or another, no patients admitted to being a current smoker at the time of interview. The most frequent environmental/occupational exposure was toxic gas, pesticide, and chemical (n=18, 40%) followed by air pollution (n=17, 38%) and asbestos (n=9, 20%). Forty percent of patients were using continuous supplemental oxygen to aid their breathing at the time of interview.

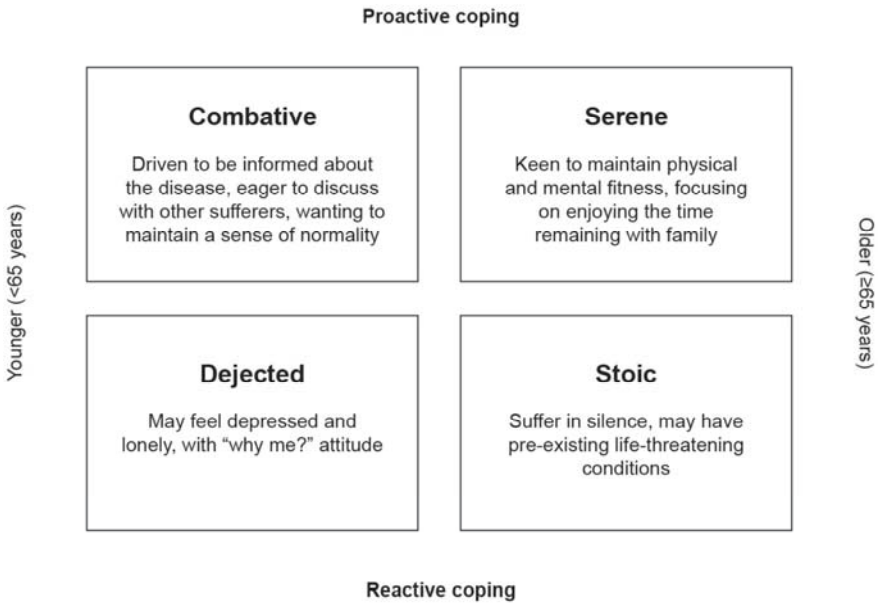

Fig. (1). Four patient segments were identified on the basis of age and mindset of interviewed patients.

3.2. Patient Segments

The interview data identified four patient segments based on age and mindset (Fig. **1**). Patients with a proactive mindset could be split into two segments by age: "serene" were older patients (≥65 years) and "combative" were younger patients (<65 years). Patients with a reactive mindset could also be split into two segments by age: "stoic" patients were older patients (≥65 years) and "dejected" were younger patients (<65 years). Each segment type showed differences in their approach to living with IPF, their overall outlook on life, and how well they took ownership of the disease.

Notable differences in attitude were found between older and younger patients. The way patients coped with the disease and their attitude to life were also affected by other criteria including education level, marital status, fitness levels, and concomitant conditions.

Patients with a "serene" mindset accepted that they had had a good life and were happy to focus on spending their remaining time with family. "Combative" patients were determined to retain a sense of normalcy, whilst finding out as much information about the disease as possible. Maintaining physical fitness was a key aim for this patient group. "Stoic" patients tended to suffer in silence. These patients may be widowed or have other concomitant conditions. Finally, "dejected" patients experienced feelings of depression, were overwhelmed by a sense of injustice, and were prone to isolation and introspection. The use of patient support groups, which would allow patients an opportunity to communicate with fellow IPF sufferers, was highlighted as a current unmet need. Increased peer-to-peer communication would be beneficial to all patients within each segment type, particularly the "dejected" and "stoical" segments.

3.3. Impact of an IPF Diagnosis Upon Patients' Emotional Well-Being and Daily Life

The interview data showed that a wide range of emotions were felt by patients at the point of diagnosis with IPF, including relief, distress, confusion, anger, and shock (Fig. **2**). The types of emotions displayed were dependent on the patient's initial mindset and their expectation for diagnosis, as well as on the manner in which the diagnosis was communicated to the patient by the physician. If this critical moment in the patient-physician relationship was handled poorly (for example a rushed consultation, incomplete supply of information regarding disease prognosis and management, diagnosis communicated by a junior physician, or expressed in a perceptively "cold and clinical" manner) it resulted in the breakdown of the relationship. Trust was maintained in those physician-patient relationships where patients were given the diagnosis in a sensitive and unhurried manner and supplied with the necessary disease prognosis and management information. The emotional well-being of the patient and acceptance of the diagnosis was also dependent on how much prior awareness the patient had regarding IPF.

After diagnosis, some patients reported a downward spiral of feelings and emotions including social isolation and withdrawal, loneliness, and fatigue (Fig. **3**). This ultimately led to depression and whilst this could affect any patient, it appeared to affect the "dejected" and "stoical" patient segment types most.

Patients diagnosed with IPF reported an impact on all aspects of life including work, finances, family and social life, hobbies, and independence. Patients with IPF also faced difficulties interacting with other people, including the general public, employers, insurers, friends, and family (Table **1**). Difficulties occurred particularly during the early stages of the disease, when patients may not appear to others to be ill.

The interview discussions revealed that the necessity for supplemental oxygen as part of the disease therapy was a pivotal step in a patient's loss of independence, as not only did this externalize the disease as a visible sign of illness, but it also impacted on daily physical activity. Excursions outside of the home were more challenging, leading not only

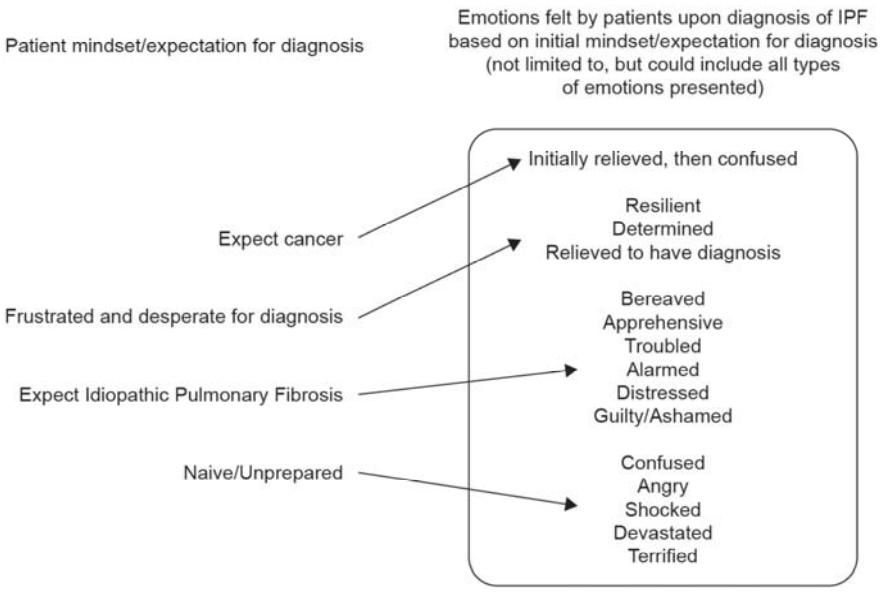

Fig. (2). A wide range of conflicting emotions were displayed by interviewed patients upon diagnosis with IPF.

to social withdrawal and isolation but also to a perceived increase in the burden of patients on their families and caregivers. Patients who participated in these interviews had mixed feelings and emotions regarding oxygen therapy. Some patients felt stigmatized by the visible presence of an oxygen tank, having received stares from members of the general public and felt the tank was a further barrier and hindrance to daily life, whereas others viewed the presence of an oxygen tank more positively as it was a visible confirmation to friends and to the public that they were unwell. Some patients stated that as a result of the additional delivery of oxygen helping them feel better, they were able to carry on living life on their own terms.

3.4. Emotional Well-Being of Patients After Diagnosis with IPF

The interview data identified three successive emotional phases after diagnosis; coming to terms with the diagnosis, reactive coping/acceptance, and proactive coping/taking ownership of the condition. Different levels of emotional support were required at each stage. Upon the initial diagnosis of IPF, patients reported a large quantity of information to be processed both rationally and emotionally, therefore requiring extensive support from healthcare professionals at the first stage of their journey. At the second stage, the disease became more "normal" to the patient; they were more familiar with hospital routines and started to build relationships with healthcare professionals. Patients at this stage required specific emotional support regarding disease treatment and prognosis. Finally, the last emotional phase involved patients developing coping mechanisms and building relationships with other sufferers. Patients managed their condition more proactively and were more demanding of healthcare professionals. Patients in this final stage required emotional support regarding ongoing disease management.

It was noted that after diagnosis, the quality of patient care depended on whether treatment was received at a specialist (IPF centers of excellence) or generalist (general pulmonary centers) center. Patients who received treatment in specialist centers felt better cared for, more informed, and overall more reassured than patients receiving treatment in generalist centers. The interviewers also noted that patients who were followed up at generalist centers were overall less motivated and less informed than patients who were followed up at specialist centers.

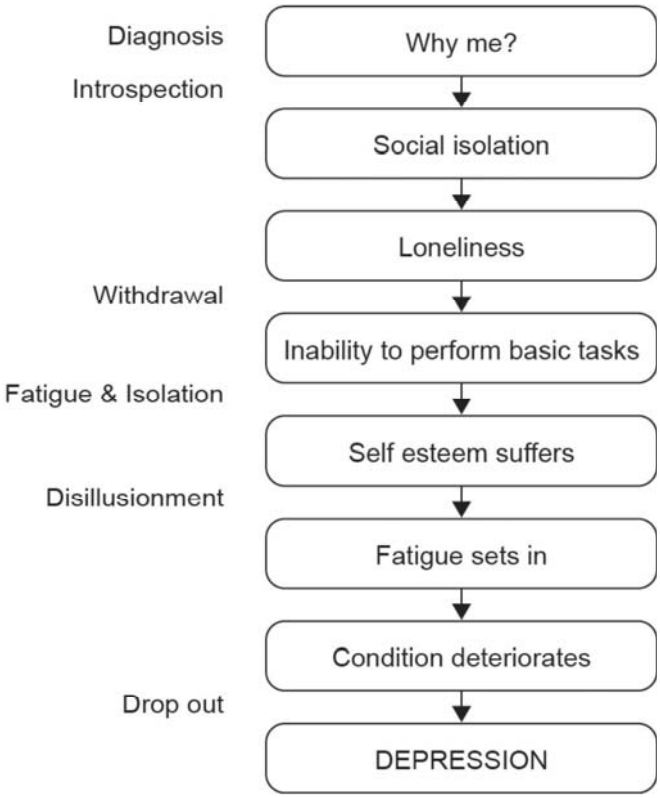

Fig. (3). Flowchart depicting the various stages of interviewed patient feelings after diagnosis. Progression through the stages eventually leads to depression. Depression is most likely to be experienced by "dejected" and "stoical" patient segment types.

Table 1. Common Issues Highlighted by Interviewed Patients Including Quotes Regarding Difficulties they Faced with Other People

Category	Quote	Reported Concern
Environment	"If I had cancer, people would empathize more."	General public do not understand, e.g. challenge the right to use disabled parking spaces.
General public	"I had to fight for my pension in court. The Federal Pension Plan Agency for Employees said "You are just too lazy for working. You are 42 and probably not ill at all. Look at yourself in the mirror." I stopped wearing make-up and wore my oldest clothes in order to be taken seriously."	Stares received from general public, particularly if oxygen tanks were visible.
Private life	"A friend will say "Gosh, you look really well." Almost accusing me as if to say how dare you. Obviously, she doesn't really mean that. But I think in some ways it's deceptive."	Patients may become suspicious of friends' motives.
Personal/Family life	"Even showering becomes a problem; you do it in stages. And someone has to be here."	Become dependent on loved ones; patients often vent frustrations on them.

3.5. Co-Word Analysis from the *Insight Room*

Seven patients from around the United Kingdom and Ireland participated in the *Insight Room*. The geographical location of patients included London, Glasgow, Dublin, Cork, Ludlow, Newcastle-upon-Tyne, and Kilbarchan. Key words which were used during the total conversations from the *Insight Room* could be split into four distinct topics: the physical problem, the relationship between patients and the medical community, family support, and hope for future research (Fig. **4A**).

Results from the total of all conversations revealed that the most common words used by patients to describe their IPF physical manifestations and symptoms included "chest", "problem", "month", and "tell". A key outcome of conversations regarding the relationship between patients and the medical community was that patients felt it took a long time to obtain a correct diagnosis from the medical profession. The most frequently used words within this conversation included "lung", "year" and "test". In contrast, the key theme regarding family support was much more positive, with patients stating that family and friends helped lift their mood and provided crucial support (key words included "time", "work", "life", and "feel"). Finally, participants expressed concern regarding a perceived low level of awareness and knowledge of IPF by themselves, caregivers, physicians, and society as a whole and their hope for future research (key words including "disease", "IPF", "condition", and "medical").

Conversations relating to living with IPF could also be separated into four distinct topics: patient struggles in a positive or negative way, family support, and daily routine (Fig. **4B**). Patients who voiced their struggles in a negative tone often referred to things that "they are not able to do", "it is hard to go ahead" and the main emotion expressed was one of anger. Conversely, those individuals with a positive outlook used "love and help" as the foundation stones for facing their illness. Within family support, patients identified how fundamental a role their family played in supporting them and helping them to cope. Finally, patients described how having IPF had impacted negatively on their daily life, particularly with regards to their reduced physical activity levels and poorer finances (key words including "life", "IPF", and "day").

The *Insight Room* was so successful in allowing patients to discuss all aspects of the disease and its impact on their quality of life that participants formed a strong bond with each other and indicated that they would like to continue communicating with each other, after the 7-day forum closed. Although this was not possible, in order to ensure patient confidentiality, this request highlighted a real desire by patients to have online peer-to-peer communication to discuss emotions and feelings with others in the same position.

4. DISCUSSION

A diagnosis of IPF has substantial emotional impact on patients and their caregivers. Patients with IPF could be divided into four segment types based on their age, ability to cope with the disease, and mindset. Patient coping strategies are affected by age and mindset. Disease acceptance and emotional well-being appeared to be partly influenced by the patients' reasonable life expectancy: patients who, in the absence of IPF, could reasonably have expected to live for another 20–30 years, tended to display more desire to fight the disease or conversely to become more depressed or dejected than patients in their 70s or 80s, who tended to be more accepting of the disease.

It was found that the type of communication between physicians and the patient, and the patients' prior awareness of the disease (particularly at diagnosis stage) have considerable impact on a patient's emotional response. A key need for patients with IPF, highlighted as a result of this study, was provision of emotional support from healthcare professionals at all stages of the patient journey, and that this should be incorporated, wherever possible, as part of the disease management process from the beginning.

A key component to achieving and maintaining a positive mindset whilst coping with IPF is being active and keeping fit. Physical exercise helps fight weight gain whilst potentially improving oxygen uptake in the lungs, helping to maintain more optimal lung function. Exercising may also increase energy levels, potentially leading to less introspection and a more positive outlook for patients with IPF.

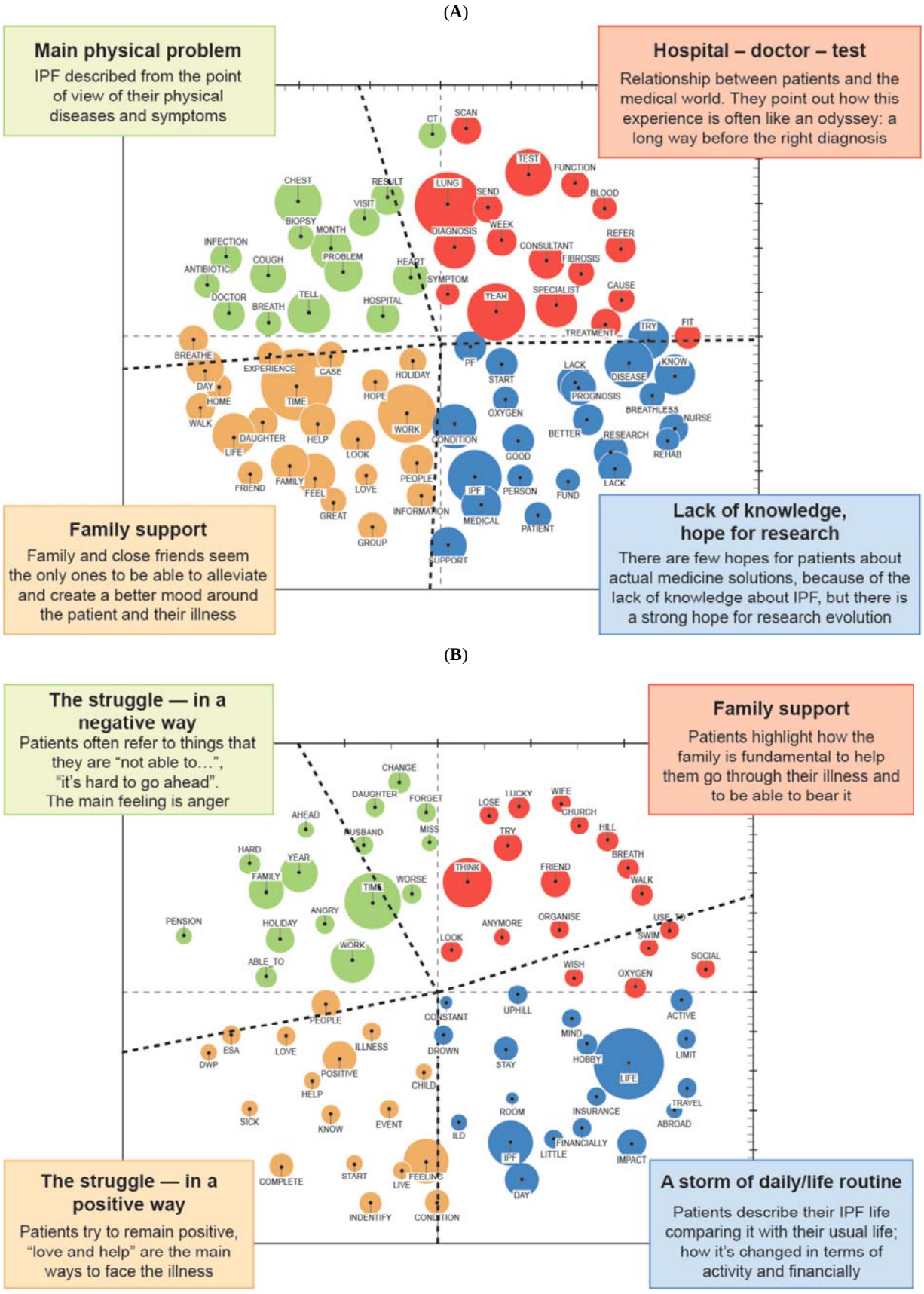

Fig. (4). Co-word analysis of *Insight Room* 7-day forum by **A**) Total conversations and **B**) Conversations relating to living with IPF. The larger the bubble size, the greater the word frequency during analyzed conversations.

The use of the internet and improved access to patient-to-patient communications and information *via* patient support groups and online forums would benefit all patients, particularly "dejected" and "stoical" patient segment types by greatly improving patient awareness and prevent feelings of isolation. In this study, it was noted that participants from the United Kingdom and Germany used the internet and online forums more frequently than patients from the other European countries. Another key result highlighted in this study was a perception that disease information was not readily accessible to patients, particularly at the diagnosis stage, and this concurs with the findings of a study carried out by Collard *et al.* [12].

Results from the original published study data and the subsequent secondary analyses are based upon the interviewed participant's ability to recall facts and feelings, and this may be subject to bias. In addition, a limited sample size of patients with IPF were interviewed (n=45). The lack of use of standardized quality of life tools such as HRQOL or the World Health Organization Quality of Life assessment instrument-100 (WHOQOL-100) precluded comparisons with other patient groups.

The additional study involved co-word analysis of data captured by an *Insight Room*, which was open for only 7 days. It should be noted that use of an online methodology may have caused some selection bias towards more active users of the internet. Again, due to a limited sample size of patients with IPF who took part in the *Insight Room* (n=7), quantitative analysis of demographic data, such as age and gender, were not performed. Further investigation in a larger cohort is planned and would enable statistical analysis of these, as well as other various parameters such as socioeconomic status and presence of comorbidities.

Results of this study enabled the identification of areas where the management of IPF might be improved: raising awareness of the disease, increasing contact amongst IPF sufferers and increasing, where needed, the access to counseling services. These aspects should be considered for inclusion in the IPF disease management process in order to meet the emotional needs of patients with IPF.

5. CONCLUSIONS

The emotional impact on patients diagnosed with chronic conditions such as IPF should not be under-estimated. Increased awareness of the disease by both patients and their family/friends, increased contact with other sufferers, and increased availability of patient counseling are all methods which can support the emotional needs of patients with IPF and are recommended to be incorporated into the disease management process, as is the case for oncology patients. This manuscript is dedicated to patients with IPF.

Key points for decision makers:

- A diagnosis of IPF has substantial emotional impact on patients
- There is a noticeable lack of disease information available to patients, particularly at the time of diagnosis
- The type of communication between healthcare professionals and the patient, and a patient's prior awareness of the disease, particularly at diagnosis, has a great impact on a patient's emotional response
- Emotional support for patients is clearly needed from healthcare professionals at all stages of the patient journey, as part of the disease management process
- The following recommendations should be considered and incorporated into the disease management process in order to meet the emotional needs of patients with IPF:
  - Increase awareness of IPF for patients and their family/friends
  - Increase contact to other patients with IPF
  - Increase availability of counseling services to patients, if required

CONFLICT OF INTEREST STATEMENT

Christophe Giot and Manuela Maronati are employees of InterMune International AG, Muttenz, Switzerland and receive stock/stock options. Ian Becattelli is an International Research Consultant for DoxaPharma S.r.l and Gadi Schoenheit is a Director of DoxaPharma S.r.l., Milano, Italy. Both IB and GS confirm they have received consulting fees or honoraria from InterMune Inc.

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Author Contributions

Ian Becattelli and Gadi Schoenheit were involved in the original study patient interviews and analysis. Gadi Schoenheit was involved in set up and analysis of the additional *Insight Room* data.

All authors were involved in conception and planning of the work and/or acquisition, analysis and interpretation of the data plus drafting and/or critical revision of the manuscript for important intellectual content, including approval of the final submitted version.

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