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OP0264-HPR

“I LITERALLY CONVINCED MYSELF I WAS GOING TO CATCH IT AND DIE”: LIVED EXPERIENCES OF THE COVID-19 PANDEMIC BY PEOPLE WITH RHEUMATIC DISEASES FROM FOUR EUROPEAN COUNTRIES

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Background: The COVID-19 pandemic has resulted in unforeseen challenges for humanity, taking a significant toll, especially the immune-suppressed individuals. In this regard, the health and general well-being of people with rheumatic diseases, the great majority users of immunosuppressives, have been at stake.

Objectives: To explore the impact of the COVID-19 pandemic on people with rheumatic diseases on immunosuppression during the first wave, concerning a) (self-)management of their disease; b) interaction with the health care team; c) emotional well-being and d) overall health.

Methods: A qualitative study was conducted following a phenomenological approach. Adults (>18 years) with a rheumatic disease from four European countries (Cyprus, England, Greece, Portugal). Patients were recruited through patient's associations and social media and were invited to participate in semi-structured, audio-recorded interview or focus groups, between July - August 2020. Following a pilot study the information provided was transcribed verbatim, anonymized and translated into English where necessary. An inductive approach was adopted to carry out a thematic framework analysis with the assistance of ATLAS.ti to identify key themes and subthemes. Data validation strategies were employed, and Ethical approval and informed consent were obtained.

Results: Participants were 24 patients (21 women, age range 33 to 74 years) divided by 7 focus-groups and 1 individual interview. Most frequent diagnoses were rheumatoid arthritis (n=7), lupus (n=4), juvenile idiopathic arthritis (n=3). Three key themes with 3-7 subthemes were identified within the analytical framework, centred around the impact of the Covid-19 on patients' lives (Figure 1): i) individual person (e.g. fear for myself and family, social isolation and lack of personal freedom, more time with family) ii) health settings (e.g. (un)clear information about risks of contamination, fear or risk of shortages of medication, remote consultations), and iii) work and community (e.g. persistent stress due to mass media exposure, lack of awareness by others about patients' rheumatic disease and its disclosure, hope and suspicion about new vaccine development: "I hear that they will ask vulnerable groups to have the vaccine first (...) Why is that? we will be again the innocent victims"). Findings were similar across countries, except for spirituality (i.e. the pandemic as "the hand of God"), a coping sub-theme particular to Portugal. These main themes resonated well with the social ecological model and Walsh's Family Resilience Process [1,2].

Figure 1. Lived experiences of the Covid-19 pandemic by people with rheumatic diseases

Conclusion: When experiencing a significant life-event people require some time to process the different lived experiences. This study provides insights on how patients from four countries coped with the new challenges. Such insights are invaluable for health care providers and policy makers, in guiding more meaningful support tailored to individual needs, especially at times of crisis. The study highlights the impact of COVID-19 on the lives of people with rheumatic disease. A follow-up study is currently underway to examine the effect of subsequent waves of the pandemic.

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OP0265-HPR

IMPACT OF COVID-19 PANDEMIC ON RHEUMATOLOGY PATIENTS IN NORTHERN IRELAND – A WEB BASED CROSS-SECTIONAL SURVEY

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Background: Concern for the susceptibility of rheumatology patients to severe COVID-19 illness has been raised since the start of the pandemic. Rheumatic disease and their immunosuppressant therapies placed many patients into the 'clinically extremely vulnerable' group when the UK's shielding guidance commenced on 23 March 2020. The impact of DMARDs/glucocorticoids/biologics on COVID-19 remains under investigation ¹. A recent study suggested caution may be required with rituximab and sulfasalazine in COVID-19 patients ².

Objectives: The objective of this study is to evaluate the impact of the COVID-19 pandemic on rheumatology patients in Northern Ireland by assessing demographics, rheumatic disease, medications, disease progress, shielding advice, access to primary & tertiary care and incidence of COVID-19 infection.

Methods: A web-based cross-sectional survey was completed in Northern Ireland. The study duration was between 23rd November 2020 and 22nd January 2021. The questionnaire included consent, demographic details, medication history, comorbidities, disease course, patient experience, shielding advice, COVID-19 illness and hospitalisation. The survey was publicised by sending 6,032 Belfast Trust NHS patients a link via SMS, posters were displayed in rheumatology departments, and links made available via NHS/Versus Arthritis social media platforms.

Results: There were 2,615 responses and of these 2,539 had been completed and were analysed. Most respondents were aged 45+ (78.27%) and female (N=1819). Rheumatoid arthritis (41%) and psoriatic arthritis (29%) were the most common diagnoses. Just over one third (35.27%, N=896) of patients were on biological drugs. Most patients were taking methotrexate (28.04%) followed by hydroxychloroquine (15.20%) and adalimumab (12.52%). The majority (79.6%) continued treatment during the pandemic. There was evidence of disease 'flaring' in 30.75% of patients who had stopped treatment. Of the respondents surveyed 7.8% (N=198), tested positive for Covid-19 and of these 77.55% reported that they had received adequate shielding advice, primarily from GP or UK government sources. Only 11.11% (N=22) of those who tested positive for Covid-19 required hospital admission and 2 patients required intensive care support. Both patients requiring ICU were not on immunosuppression. Less than one third of patients testing positive for COVID-19 were on biological drugs (30.3%, N=60). Cardiovascular disease was the most prevalent comorbidity. Of the 22 patients hospitalised with COVID-19, 13.64% (N=3) were on solitary sulphasalazine therapy.

Conclusion: The survey showed low levels of COVID-19 hospitalisation despite most patients continuing DMARD/biologic/glucocorticoid therapy. This has been replicated in other studies¹, however data continues to be gathered on the safety of some biologic drugs particularly rituximab². Most of our patients received clear understandable shielding guidance from a variety of sources. Many patients expressed fear of mortality, isolation and mental health issues. The survey findings indicated that stopping medication can have a negative impact on disease control.

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Progress in myositis and scleroderma research - II

OP0266

EFFICACY OF NINTEDANIB IN PATIENTS WITH SYSTEMIC SCLEROSIS-ASSOCIATED INTERSTITIAL LUNG DISEASE (SSc-ILD) AND INTERNAL ORGAN INVOLVEMENT: DATA FROM THE SENSICIS TRIAL

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Background: SSc is a heterogeneous autoimmune disease characterised by fibrosis of the skin and internal organs. In most patients with SSc-ILD, organs other than the lungs are also affected. In the SENSICIS trial in patients with SSc-ILD, nintedanib reduced the rate of decline in forced vital capacity (FVC) (mL/year) over 52 weeks by 44% versus placebo.

Objectives: We investigated the extent of organ involvement related to SSc at baseline in patients in the SENSICIS trial and the effect of nintedanib versus placebo on the rate of FVC decline in subgroups by internal organ involvement.

Methods: The SENSICIS trial enrolled patients with SSc-ILD with first non-Raynaud symptom ≤ 7 years before screening, extent of fibrotic ILD $\geq 10\%$ on high-resolution computed tomography (HRCT) and FVC $\geq 40\%$ predicted. Patients with clinically significant pulmonary hypertension were excluded. Patients were randomised to receive nintedanib or placebo until the last patient reached week 52

but for ≤ 100 weeks. In post-hoc analyses, we analysed the rate of decline in FVC (mL/year) over 52 weeks in subgroups with and without different types of SSc-related internal organ involvement (upper gastrointestinal; lower gastrointestinal; cardiovascular [CV]; peripheral vascular; muscular; joint). These subgroups were defined based on patients' SSc-related medical history as reported in the case report form. A random slope and intercept model was used to assess the rate of decline in FVC (mL/year) and an interaction test applied to assess potential heterogeneity in the treatment effect of nintedanib between the subgroups.

Results: Of 576 patients, 96.9% had peripheral vascular involvement, 75.5% had upper gastrointestinal and 39.8% lower gastrointestinal involvement, 45.7% had CV involvement, 40.6% had joint involvement, and 27.1% had muscular involvement at baseline. In the placebo group, the rate of decline in FVC (mL/year) was numerically greater in patients with than without upper gastrointestinal involvement and in patients without than with joint involvement or muscular involvement (Figure). The exploratory interaction p-values did not indicate heterogeneity in the treatment effect of nintedanib versus placebo on reducing the rate of decline in FVC (mL/year) between the subgroups based on organ involvement ($p > 0.05$ for all treatment-by-time-by-subgroup interactions) (Figure).

Conclusion: Patients in the SENSICIS trial had diverse complications related to SSc. There was no evidence of a differential treatment effect of nintedanib on reducing the rate of decline in FVC based on gastrointestinal, CV, joint, or muscular involvement at baseline.

Figure. Rate of decline in FVC (mL/year) over 52 weeks in subgroups by internal organ involvement at baseline in the SENSICIS trial.

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OP0267

SHORT-TERM CHANGES IN THE RADIOGRAPHIC EXTENT OF INTERSTITIAL LUNG DISEASE PREDICT LONG-TERM MORTALITY IN SYSTEMIC SCLEROSIS

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Background: The forced vital capacity (FVC) is often used as the primary endpoint in treatment trials for systemic sclerosis-interstitial lung disease (SSc-ILD), and while trends in FVC have been found to predict mortality in SSc-ILD,^{1,2} FVC measurements are also influenced by extra-pulmonary factors, such as cutaneous sclerosis, myopathy, and patient/technician effort. Change in the quantitative extent of ILD (QILD) on HRCT is an emerging endpoint in clinical trials; however, no studies have evaluated whether changes in radiographic extent ILD predict mortality in SSc-ILD.

Objectives: To evaluate the relationship between changes QILD in the whole lung (WL) and long-term survival in patients who participated in the Scleroderma Lung Study (SLS)³ and IL⁴.