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Perspectives of patients with inflammatory rheumatic diseases in the early phase of COVID-19

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INTRODUCTION

The impact of coronavirus disease 2019 (COVID-19) and the resulting severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) on the Australian healthcare system has been tempered by the early adoption of public health measures and an expansive approach to testing. [1, 2] The healthcare system has however had to institute major changes to achieve pandemic preparedness, such as deferment of elective and 'non-urgent' medical care, and the widespread adoption of telehealth.

There have been rapid developments in laboratory and translational research assessing vaccine efficacy and therapeutics. However, uncertainties regarding the development of sustained immunity and the need for data from well-designed randomised clinical trials will mean that infection control measures are likely to be in place in some capacity for a prolonged period of time. Consequently, healthcare providers will need to adapt rapidly in order to meet the evolving challenges of COVID-19.

In rheumatology, it is imperative that we take a proactive approach in communicating up-to-date and relevant advice to our patients to minimise preventable adverse outcomes that may result from misinformation, particularly regarding the use of immunosuppressive medications. [3] Integral to developing a strategy of communication is the need to first understand the perceptions of patients with rheumatic diseases.

The objectives of this study were to investigate the concerns of rheumatology patients in regards to COVID-19, evaluate the potential impact of proactive dissemination of patient advice in a large tertiary rheumatology service, and assess the acceptance of telehealth in a tertiary public rheumatology service.

METHODS

Patients and Recruitment

All existing patients of the Monash Health rheumatology service with a scheduled appointment between either March 2019 to March 2020 or March 2020 to March 2021 were identified from the

institution's electronic medical records. The mobile numbers of patients were extracted with no associated identifying information. Patients were sent a single text message which directed them to an electronic copy of the Australian Rheumatology Association (ARA) COVID-19 Patient Information Sheet (version 3, 25th of March 2020) and an invitation to complete an optional anonymous online survey.

Australian Rheumatology Association COVID-19 Patient Information Sheet

The ARA patient information sheet reported the recognised risk factors for a poor prognosis from COVID-19 to date, advised patients against stopping their medications unless they were unwell, reassured patients that there has been no data to date that demonstrated an increased risk of mortality in rheumatology patients on immunosuppression, encouraged physical isolation in specific scenarios, and provided advice on next steps if patients were to become unwell. The information sheet also provided general public health advice regarding physical distancing and hygiene, and reinforced the importance of seasonal vaccinations. Patients were advised to contact their specialist if they had specific questions.

Patient Survey

Baseline demographics collected included age, sex, rheumatological diagnosis, duration of disease, current medications, current dose of prednisolone, and patient perception of disease control (Scale: 0-100; 0: 'poorly controlled', 50: 'reasonable, but could be better', and 100: 'well-controlled').

Patients were asked 4 questions to determine if they believed that their (1) rheumatological disease increased their risk of contracting COVID-19, (2) rheumatological disease increased their risk of being more unwell with COVID-19, (3) medications increased the risk of contracting COVID-19, and (4) medications increased the risk of becoming more unwell with COVID-19. Patients who reported being concerned about their medications were asked to indicate which of their medications were concerning to them.

The survey assessed if patients had already obtained advice regarding their immunosuppression and if so, from what source. Patients were asked if they found the ARA patient information to be relevant and/or helpful, if receiving the information affected their intention to stay on their immunosuppression, and what information they would like included in future iterations. Patients were invited to leave their mobile number or email address if they wished to receive updated information.

Acceptance of telehealth and the intention to obtain the flu vaccine was also ascertained.

Statistical analysis

Continuous data were examined using histograms and the Shapiro-Wilk test to determine the appropriate measures of central tendency and dispersion.

Univariate binomial regression analysis was used to determine the association between exposure variables and: (1) patient perception regarding the COVID-19 risk associated with their rheumatological diagnosis, and (2) patient perception regarding the COVID-19 risk associated with their treatment. The respective exposure variables were (1) age, sex, patient perception of disease control, disease duration and diagnosis, and (2) age, sex, patient perception of disease control, disease duration, treatment strategy and prednisolone dose. Exposure variables with a p-value of >0.25 (pre-determined threshold) on univariate analysis were included in multivariate regression analyses.

Descriptive analysis was used to report concerns regarding specific medications, perceptions of telehealth, intention to obtain the flu vaccine, sources of information regarding SARS-CoV-2, and relevance of the ARA patient information sheet.

Statistical analyses were conducted using SPSS v.23.0 (IBM Corp., Armonk, NY, USA). Approval of the study as a quality improvement project was obtained through the Monash Health Research Ethics (Ref: RES-20-0000-217Q).

RESULTS

The survey response rate was 21% (n=550/2630) with an average completion time of 11 minutes. The mean (\pm SD) age of respondents was 52 (\pm 15.2) years and 75% were female. A majority of patients reported a diagnosis of Rheumatoid Arthritis (RA) (29.7%), followed by Systemic Lupus Erythematosus (SLE), Systemic Sclerosis (SSc) and Psoriatic Arthritis (PsA) (Table 1). The median [IQR] disease duration and patient perception of disease control were 6 [3.0-14.0] years and 77/100 [53.0-93.0] respectively.

Sixty four percent of patients were on \geq 1 conventional synthetic disease-modifying anti-rheumatic drugs (csDMARDs), with the most common agents being Hydroxychloroquine (36.9%) and Methotrexate (30.2%) (Table 1). Of the 17.8% of patients on a biologic or targeted synthetic anti-rheumatic drug (b/tsDMARD), the majority were on a tumour necrosis factor inhibitor (TNFi). Prednisolone and non-steroidal anti-inflammatory drugs (NSAIDs) use was reported by 26.9% and 22.4% of patients. The median [IQR] prednisolone dose in the population was 0 [0-1] mg and the median [IQR] dose among patients on prednisolone was 5 [3.0-7.5] mg.

Patient concerns regarding the risk associated with their diagnosis and medications

Approximately 41% of patients were concerned that their rheumatological disease increased their risk of contracting COVID-19 while 52.3% were concerned that their rheumatological disease increased their risk of becoming more unwell with COVID-19.

Univariate analysis demonstrated that female patients were more likely to be concerned that their diagnosis increased their risk of contracting (OR=1.50 [95% CI: 1.008-2.246]; p=0.046) or becoming more unwell (OR 1.59 [95% CI: 1.016-2.480]; p=0.043) with COVID-19, however this association was not seen in multivariate analyses accounting for age, disease duration and diagnosis. Univariate analysis also revealed that patients with SLE were more likely to be concerned about the risk of contracting or being more unwell with COVID-19 as a result of their disease (OR=2.71 [95% CI: 0.994-7.380]; p=0.051) and OR=4.42 [95% CI: 1.512-12.898]; p=0.007]. On multivariate analysis, only the association with an increased concern regarding contracting COVID-19 remained, but this was of borderline statistical significance (OR=2.83 [95% CI: 0.993-8.053]; p=0.052).

In contrast, 55.7% of patients were concerned that their immunosuppressants increased their risk of contracting COVID-19 while 76.1% were concerned that their immunosuppressants increased their risk of becoming more unwell with it. Among patients on immunosuppressants, all patients on cyclophosphamide reported being concerned about the risk it conferred, followed by 70% of patients on mycophenolate, 62% of patients on b/tsDMARDs, 57% of patients on Azathioprine and 55% of patients on Methotrexate. Patients were least concerned about hydroxychloroquine (20%) and NSAIDs (28%). (Figure 1)

In the univariate analysis, there was a small but significant association between age and patient concern that their medication could increase their risk of contracting (OR=0.98 [95% CI: 0.971-0.994]; p=0.003] or becoming more unwell with (OR=0.98 [95% CI: 0.970-0.993]; p=0.002) COVID-19. There were no significant associations with sex, disease duration or disease control. (Table 2)

On multivariate analysis, the treatment strategies associated with an increased odds of concern regarding immunosuppression causing an increased risk of contracting COVID-19 were combination csDMARDs (OR=8.44 [95% CI: 3.752-18.966]; p<0.001), combination csDMARDs with prednisolone (OR=3.40 [95% CI: 1.241-9.300]; p=0.017), b/tsDMARD monotherapy (OR=5.82 [95% CI: 2.235-15.170]; p<0.001), a b/tsDMARD with csDMARD(s) or Prednisolone (OR=3.67 [95% CI: 1.452-9.270]; p=0.006) and a b/tsDMARD with csDMARD(s) and Prednisolone (OR=15.12 [95% CI: 3.612-63.284]; p<0.001]. All treatment strategies associated with increased odds of concern regarding immunosuppression resulting in patients being more unwell with COVID-19. The highest ORs were seen in the combination csDMARD (OR=12.06 [95% CI: 5.161-28.186]; p<0.001) and b/tsDMARD and csDMARD(s) and prednisolone group (OR=22.29 [95% CI: 4.403-112.881]; p<0.001).

There was no significant association between prednisolone dose and concern regarding contracting or being more unwell with COVID-19.

COVID-19 Patient information

Sixty one percent of respondents (n=277) reported having already looked for or obtained information regarding the impact of COVID-19 in respect to their rheumatological conditions or medications. The most common sources of information were the department of rheumatology (31%), general practice (30%) and a google search (17%). Only 9% of patients had obtained information from the Arthritis Australia website while 5% had obtained information from the Arthritis Foundation website. Other reported sources included pharmacy (n=7) and other specialists (n=7).

A majority of patients (92%) reported that they found the ARA patient information sheet helpful and elected to receive updated information as it becomes available via email (n=300) or text message (n=193). While most patients (63%), reported that the information sheet had not changed their existing plan to continue their current medications, 30% of patients reported that they were more likely to stay on their medications as a result of receiving the ARA patient information sheet.

Additional information requested by patients included more specific information regarding the impact of rheumatic disease, its activity, and immunosuppression on the risk of contracting and being more unwell with COVID-19 (n=29), general information regarding COVID-19 (n=10), more specific advice regarding work (n=4), support and reassurance regarding access to medications, particularly hydroxychloroquine (n=8), community services for immunosuppressed (n=4), advice regarding well-being practices while distancing (n=2) and risk stratification regarding when immunosuppression needs to be stopped in the event of being exposed to or diagnosed with COVID-19 (n=2). Patients also requested additional information (n=14) regarding the structure, timing and availability of telehealth appointments.

Patient opinions on Telehealth and the Influenza Vaccine

Thirty two percent of patients reported that they were more likely to have the Influenza vaccination this year, while 62% were as likely to have it as last year, and 7% were less likely to have it than last year. A minority of patients felt that telehealth was only appropriate in times of strict infection control (28.1%) or that it was never appropriate (1.6%). Responding to a question in which patients were allowed to tick as many options as applied, approximately 60% of patients felt that telehealth was appropriate if their condition was well-controlled, 56.2% if their rheumatologist felt it was appropriate, 55.1% if the consultation was with a rheumatologist who knew their case well and 34%

if they were unwell and were unable to attend. Additional reasons provided by patients were work and family commitments, transport limitations, and in order to be seen quicker. One respondent noted that telehealth was inappropriate for a first consultation.

DISCUSSION

Uncertainty is part and parcel of clinical rheumatology, and it is our charge as clinicians is to minimise the experience of uncertainty in our patients. We provide our patients with a sense of normality and stability via patient education, adequate disease control, and the prevention of morbidity and mortality associated with rheumatological diseases and its treatment. The ability to do this has been challenged by the novel COVID-19 pandemic and the resulting abrupt institution of telehealth consultations, uncertainties surrounding the risks associated with rheumatological diseases and its therapy, and possible delays in treatment escalation and diagnostic investigations.

While the first recognised case of COVID-19 in Australia was diagnosed in late January 2020, the exponential rise in cases did not occur until early March, leading to the distribution of the ARA patient information sheet and data collection in late March. [1] Our aim in this study was to ascertain the early perceptions and concerns of patients in order to be able to better address them proactively moving forward in what is likely to be a challenging few years.

In our study, we found that a significant proportion of patients were concerned that their underlying rheumatological diagnosis increased their risk of contracting (41%) or becoming more unwell with (52.3%) COVID-19. There are robust data to support concerns that the immune dysregulation that occurs in rheumatic diseases such as RA and SLE, particularly in high disease activity states, confers an increased risk of other infections. [4-11] Univariate and multivariate analyses were conducted to assess if there were particular subgroups within our cohort who were more likely to be concerned. The univariate analysis identified female sex (78.2% of women compared to 69.3% of men) and diagnoses of SSc and SLE (84.0% and 85.9% respectively compared to 57.9% of patients with non-inflammatory diagnoses) as populations who were more likely to be concerned regarding the risk of their diagnosis resulting in a worse prognosis from COVID-19. These associations did not remain statistically significant on multivariate analysis accounting for the gender differences between the diagnoses, highlighting the importance of outreach with information to all patients with rheumatic diseases.

We found that 73% of respondents were concerned that their medications would increase their risk of becoming more unwell if they were to contract COVID-19. Exploring specific drugs, we found that b/tsDMARDs, Mycophenolate and Cyclophosphamide generated the most concern. Only 38% of patients on prednisolone were concerned regarding the risk it posed, despite its consistent

associations with infection risk in rheumatic disease in observational studies. [5, 6, 8-13] This may reflect the fact that 70% of patients on prednisolone were on doses of ≤ 5 mg. Only 28% of patients were concerned regarding the risk of NSAIDs despite the well-publicised concerns regarding these agents.[14, 15] This may reflect the fact a lack of awareness regarding these reports or perhaps an understanding that the concerns relate to the use of the agent for the management of pyrexia associated with COVID-19. Twenty percent of patients were concerned regarding the risks posed by HCQ in respect to COVID-19 risk, despite the well-publicised albeit poorly substantiated media interest in this drug as a therapeutic for COVID-19. [16, 17]

In multivariate analyses to identify patients who were most concerned about the risk posed by their immunosuppression, there was a small but consistent association with younger age and better disease control. The therapeutic strategies associated with an increased concern of contracting COVID-19 were: combination csDMARDs, combination csDMARDs and prednisolone, b/tsDMARD monotherapy, and b/tsDMARD with csDMARD(s) and/or prednisolone. All therapeutic strategies were associated with an increased concern regarding the risk of being more unwell with COVID-19, with the highest ORs noted in patients on b/tsDMARDs with csDMARD(s) and Prednisolone (OR 22.29), and in patients on combination csDMARDs (OR 12.06). There was no relationship between prednisolone dose and patient concerns on multivariate analysis.

Over 61% of respondents had already obtained COVID-19 patient information prior to receiving the survey, predominantly from their GP or rheumatology service. A third of patients who responded to the survey reported that receiving the ARA patient information sheet made them more likely to stay on their immunosuppression. We assessed the differences of baseline characteristics between patients who were more likely to stay on their immunosuppression (31%) and patients who had already planned on stay on their immunosuppression (63%) but found no convincing predictors. Importantly the impact was no different in patients who had already received information, irrespective of the source of information.

There are a number of possible explanations for these findings. Firstly, the advice provided in the ARA information sheet may have been more specific and up-to-date compared to previous advice received. One only needs to reflect on commentary from the World Health Organisation (WHO) as late as mid-January, stating that there was no clear evidence of human-to-human transmission of COVID-19, to appreciate how quickly our understanding of COVID-19 has evolved. Secondly, the information sheet may have had more sway having been ratified by a national organisation for rheumatic diseases. Ultimately, these findings highlight the importance of establishing a strategy to regularly disseminate updated information as it becomes available,

particularly in a tertiary centre which cares for a large number of patients who may be seen as infrequently as once a year.

We analysed patient suggestions for additional information in future iterations of the ARA information sheet and found that patients largely wanted more specific information regarding the risks posed by their disease and treatment. Such data will likely be available in the coming months from registries and cohorts, but will need to be interpreted and presented cautiously given the potentials for bias. Patient suggestions that were not already encompassed in the information sheet such as services available for immunosuppressed patients (e.g. pathology at home, delivery of medications, priority access to grocery shopping) and well-being practices whilst practicing physical distancing, were fed back to the ARA for future iterations.

A number of patients raised concerns regarding the availability of HCQ and expressed difficulty obtaining the drug despite assurances in the information sheet about continuity of supply and active measures taken by the ARA to ensure this. The consequences of publications reporting the “efficacy” of HCQ for the treatment of COVID-19 and the amplification of this research by the media has been well-described. [18, 19]. More recent reports have moderated the hype surrounding HCQ, and we may soon be faced with the task of needing to reassure our patients regarding the low risk of toxicity associated with agent in the management of rheumatic diseases. [20-22]

We briefly assessed patient intentions regarding the influenza vaccine and found that a third of respondents were more likely to have their vaccination this year. This may well be due to an increased patient awareness regarding seasonal vaccinations, the importance of which was emphasized within the ARA information sheet as well as in the body of the survey.

Finally, we assessed the perceptions of our patients regarding telehealth. In Australia, tele-rheumatology has predominantly been utilised for the provision of rheumatology services in rural and regional Australia. [23, 24] Its potential to improve the care of metropolitan patients with rheumatic diseases by complementing rather than substituting face-to-face services has been untapped. This is largely due to limitations in Medicare billing provisions and the lack of infrastructure within public clinics.

The COVID-19 pandemic has resulted in all outpatient consultations at Monash Health being conducted via telehealth where medically-appropriate. This has been a new experience for most of our clinicians and patients. There have been many concerns at a clinician level, including the adequacy of assessments not supplemented by a clinical examination and the impact on the physician-patient relationship. These concerns are not without merit, given conflicting results regarding the diagnostic accuracy of different models of telehealth, particularly in the assessment of new patients. [25, 26] Similarly, there is limited data regarding patient satisfaction with the use of

telerheumatology for new consultations that are not supplemented by a primary care physician. [23, 26]

We found that the overall acceptance of telehealth amongst our patients was high, but 28.1% of patients surveyed felt that this was only appropriate while strict infection control measures are in place and approximately 40% of patients did not feel it was appropriate if their condition was not well-controlled or if their consultation was not with a clinician who knew them.

This is the first descriptive study assessing the concerns of rheumatology patients in the era of COVID-19. The sample size is large for a single-centre cross-sectional study and it provides some interesting insights into patient perceptions in the early months of the COVID-19 pandemic. The potential research questions raised include the reasons for the change in attitude towards seasonal vaccinations, the actions that patients have already taken in regards to their immunosuppression and the impact of this on disease flares, the impact of a history of infections or metabolic co-morbidities on patient beliefs and behaviours, the impressions of patients who have had telehealth consultations, and the accuracy of diagnoses made by telehealth for new rheumatology patients. Data from longitudinal patient surveys such as those conducted by the Australian Rheumatology Association Database (ARAD) and the COVID-19 Global Alliance will be instructive in describing the evolution of such perceptions.

The major limitation of our study is response bias. At the time that data collection was ceased, 21% of patients had responded. The potential reasons for this include inaccurate contact details, language or technological barriers, concerns regarding phishing, and lack of interest or relevance for patients with common conditions such as osteoarthritis, fibromyalgia and tendinopathies. The response rate is reasonable however for an optional anonymous survey, and the baseline demographics of our study closely mirror the population described in the COVID Global Rheumatology Alliance. [27] Ultimately, response and selection bias are likely to be a feature of most observational studies conducted in the era of COVID-19.

A further limitation is that we did not collect data regarding relevant co-morbidities such as hypertension and diabetes, physician measures of disease activity, or a history of previous infection. This may in part account for the low r^2 of the regression models, but it is important to recognise that this is a common issue in studies that assess at patient beliefs. Finally, this is a single centre study, which does limit generalisability to large tertiary metropolitan rheumatology services.

Conclusion

Patients with rheumatic diseases have significant concerns regarding their risk of contracting or being more unwell with COVID-19. There is overwhelming acceptance of telehealth substituting

face-to-face consultations during the COVID-19 pandemic. The dissemination of patient information has the potential to avoid unnecessary patient-directed changes to therapy, which may minimise the risk of disease flare.

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