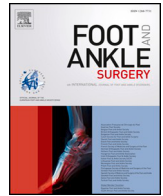


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Foot and Ankle Surgery

journal homepage: www.journals.elsevier.com/foot-and-ankle-surgery

Follow-up of health-related quality of life and pain in a cohort of patients with rheumatoid arthritis before and after COVID-19

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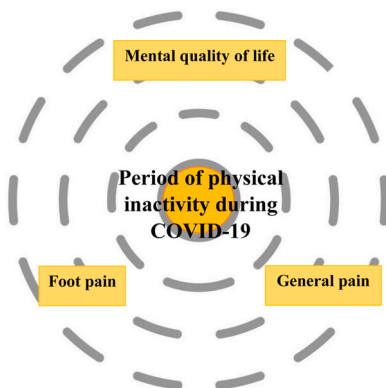
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GRAPHICAL ABSTRACT



ARTICLE INFO

Article history:

Received 4 May 2023

Received in revised form 29 June 2023

Accepted 18 July 2023

Keywords:

COVID-19

Pain

Quality of life

Rheumatoid arthritis

ABSTRACT

Background: The foot is one of the anatomical structures of the body most affected in rheumatoid arthritis (RA), associated with the disability of patients, even more during COVID-19. The aim of this study was to analyse whether the period of physical inactivity during COVID-19 is an influential factor on health-related quality of life and foot pain in patients with RA.

Methods: 162 patients with foot pain and RA, recruited from the Hospital Virgen de las Nieves, Granada (Spain) were included. Data was collected during two different periods: January – December 2018 in person and June – September 2021 by phone. Patients were asked to complete the Spanish adapted version of the 12-Item Short Form Survey (SF-12) and the Visual Analogue Scale (VAS).

Results: The results from the SF-12 questionnaires were divided between its two subscales (i.e., mental, and physical component). The physical component shows an improvement between 2018 and 2021, from 32.05

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<https://doi.org/10.1016/j.fas.2023.07.008>

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Please cite this article as: A. Reinoso-Cobo, A.-B. Ortega-Avila, C. Pineda-Galan et al., Follow-up of health-related quality of life and pain in a cohort of patients with rheumatoid arthritis before and after COVID-19, Foot and Ankle Surgery, <https://doi.org/10.1016/j.fas.2023.07.008>

in 2018–35.18 in 2021 ($p < 0.05$). The opposite happened with the mental component, showing a deterioration, from 39.69 in 2018–34.48 in 2021 ($p < 0.05$). Regarding pain, VAS shows higher levels of pain with statistically significant differences, both in general pain (from 6 in 2018–7 in 2021) and in foot pain (from 5 to 7), ($p < 0.05$).

Conclusion: Mental quality of life and pain, both general and foot pain, are influenced by the period of physical inactivity during COVID-19.

Level of evidence: Level II.

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1. Introduction

Rheumatoid Arthritis (RA) is an chronic and degenerative autoimmune disease [1,2]. RA is associated with chronic pain, which involves a decrease in the levels of physical activity and consequently, requires patients to adapt their life. Disease progression may lead to unemployment, social marginalization, economic dependency and even poverty. Patients with dysfunctions resulting from progressing RA are characterized by a significant degree of disability. Clinical studies reveal far lower quality of life in patients with RA compared to healthy individuals [3,4].

RA is a systemic disease that not only presents extra-articular manifestations but also has psychological effects, such as mental health and functional problems. It has been demonstrated that patients with RA present a significant negative impact on their health-related quality of life (HRQoL). Patients with RA suffer from major and diverse effects on HRQoL compared to general population, spanning both physical and mental domains of well-being [5,6]. Increasingly often, HRQoL reported by patients with RA provides valuable information on the effectiveness of pharmacotherapy, rehabilitation and nursing care. In 2020, with the World Health Organization (WHO) declaration of a Corona Virus Disease 2019 (COVID-19) pandemic on March 22th, 2020, drastic measures were taken in Spain, including a period of confinement (Real Decreto 463/2020) [7].

Patients with RA have higher morbidity in infectious processes [8]. Ignorance and fear of the possible consequences of catching COVID-19 promote greater isolation of patients with RA [9].

In a chronic condition, such as RA, HRQoL, anxiety/depression and mobility problems are more common than in the general population, especially in inactive people with RA [10,11]. The pandemic, caused a decrease in physical activity in the general population [12]. Patients with RA voluntarily reduced their activities of daily living and social relationships for fear of being affected by COVID-19 [13]. Inactivity is directly related to muscle atrophies [14], and in patients with RA, inactivity also causes higher levels of pain [15] and reduces HRQoL [16].

The foot is one of the anatomical structures of the body most affected in RA, which is associated with the disability of patients. This has been increased during the pandemic, however, there are no studies on the impact of HRQoL and foot pain in patients with RA after the pandemic period. Therefore, the aim of this study was to analyse whether the period of physical inactivity during COVID influenced the HRQoL and foot pain in these patients with RA.

2. Methods

2.1. Ethical approval

This study received ethical approval from the committee of Portal de Ética de la Investigación Biomédica de Andalucía (PEIBA), which was authorized and extended to a longitudinal study ARC0001. This study was carried out in full accordance with the provisions of the Declaration of Helsinki regarding ethical principles for medical

research involving human subjects and was approved by the Ethics Committee.

2.2. Design

Follow Up study in cohort of participants.

2.3. Participants

A cohort of 162 patients with foot pain who satisfied the 2010 Rheumatoid Arthritis Classification Criteria (approved by the American College of Rheumatology and the European League Against Rheumatism) [17] was included. The patients were enrolled at hospital outpatient clinics from the Virgen de las Nieves Hospital (Granada, Spain), in two different periods: firstly, from January to December 2018 and secondly from June to September 2021, post COVID-19.

All participants included in the study had a history of subtalar and/or ankle and/or talonavicular or hindfoot pain, with no daily use of walking aids, and presented normal range of motions in the ankle, subtalar and midtarsal joints.

Patients who met the inclusion criteria were approached by members of the rheumatology service at the Virgen de las Nieves Hospital (Granada, Spain), given an information sheet and invited to participate. Those who agreed to participate were then interviewed and given further details of the study. All participants provided written consent prior to starting the interviews.

The exclusion criteria applied were: presence of concomitant musculoskeletal disease, central or peripheral nervous system disease, or endocrine disorders (especially diabetes mellitus).

2.4. Data collection

2.4.1. Demographic and clinical characteristics

The demographic characteristics recorded included the patient's age, gender, disease duration, current therapy, Body Mass Index (BMI), level of studies, and job occupation. The clinical data recorded were those obtained from the Short Form 12-Item (SF-12) questionnaire [18], to assess HRQoL and the Visual Analogue Scale (VAS) for pain [19], both general and specific to foot pain.

2.4.2. Procedures

A researcher (AR-C) assessed the patients to obtain data for the study before and after pandemic. Before the pandemic, in 2018, data was collected in one room at the hospital, face to face, where the patients were asked to complete the adapted version for the Spanish population 12-Item Short Form Survey (SF-12) (), and Visual Analogue Scale (VAS) questionnaires. After the pandemic, in 2021, patients were assessed again with the same questionnaires but by phone instead of face to face.

The VAS was assessed to determine the levels of pain for both general pain (VAS-g) and foot pain (VAS-f), with a range of 0–10 where 0 is no pain and 10 is the worst pain. The SF-12 was assessed to know the levels of quality of life, which is a shortened version of the original questionnaire of SF-36. The SF-12 contains 12 items

divided into two subscales (i.e., mental, and physical component), which assess 8 health domains: physical function, social function, physical role, emotional role, mental health, vitality, bodily pain and general health [20].

2.5. Sample size

Regarding the sample size, with the current sample, statistically significant differences were found in the SF-12 obtained in 2018 and 2021, as in the VAS scale. A decrease of 13 % from the original results has been shown in the mental component and an increase of almost 10 % has been shown in the physical component. Therefore, with a sample of 124 patients, differences of 10 % were detected in both scales. Even though SF-12 is the most widely used instrument to measure quality of life, including the physical (PCS) and mental (MCS) components, its Minimal Clinically Important Difference (MCID) in patients with RA who did not undergo throw operative interventions remains unknown. Studies which include operative interventions in patients with RA stayed the following MCID: 5 for SF-12 PCS and 5.4 for SF-12 MCS [21,22].

2.6. Statistical analyses

To assess whether the numerical variables present a normal distribution, the Kolmogorov-Smirnov test has been used. Since this hypothesis was not met, the data were expressed as median and 25th and 75th percentiles. To analyse the score obtained in HRQoL before and after the COVID-19 period, the Wilcoxon test for related samples was applied. The comparison of HRQoL, VAS and BMI before and after the COVID period was analysed with the Wilcoxon test for related samples. For all contrasts, a significance level of 0.05 is considered. The data have been analysed with the IBM SPSS 19 software.

3. Results

Of the 162 patients included in the pre-COVID-19 cohort, a total of 124 patients were included in the post-COVID-19 analysis, of whom 33 were men (26.6 %) and 91 women (73.4 %). The final sample presented a median age of 57.5 years [50–64] (age range 19–85 years), and a BMI of 24.99 [23.07–30.48]. In terms of educational background, 47.6 % of the participants had primary education, 17.7 % secondary education, and 27.4 % university education. Regarding their occupation, 35.5 % were retired, 19.4 % on sick leave/disability, 12.1 % were engaged in domestic work, and 29 % had paid work. At the beginning of the study (2018) the median number of years of evolution of the disease was 12 [8–20].

3.1. HRQoL and pain

The score at both the physical and mental component level of the SF-12 has changed in a statistically significant way. The physical component shows statistically significant differences between 2018 and 2021, from 32.05 in 2018–35.18 in 2021 ($p < 0.05$ $Z = -2.176$), showing an improvement. The opposite happened with the mental component, showing a declination, from 39.69 in 2018–34.48 in

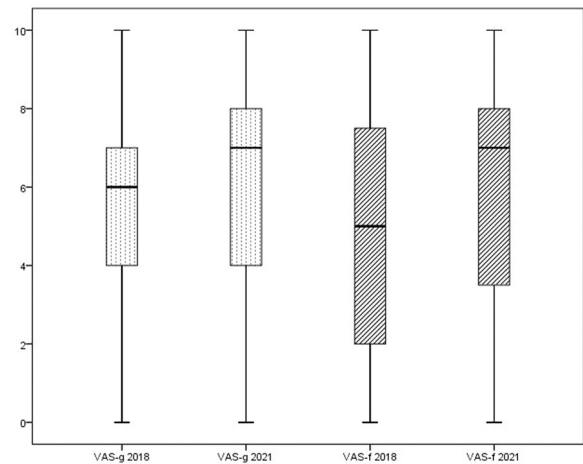


Fig. 1. Box plot. Levels of general and foot pain before (2018) and after (2021) pandemic.

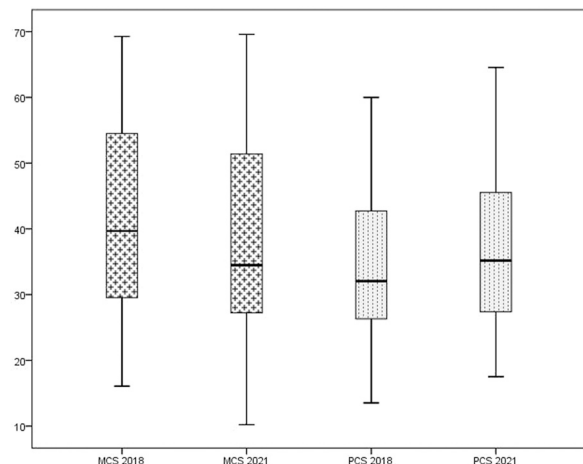


Fig. 2. Box plot. Levels of quality of life before (2018) and after (2021) pandemic.

2021 ($p < 0.05$ $Z = -2.004$) also being a statistically significant difference (Table 1).

Regarding pain, the VAS shows higher levels of pain with statistically significant differences, both in general pain (from 6 in 2018–7 in 2021) and in foot pain (from 5 to 7), ($p < 0.05$) (Figs. 1 and 2). The Data indicates that patients with RA suffer more pain after the COVID-19 period, both at the general and foot level. There have been no statistically significant changes in BMI.

4. Discussion

The aim of this study was to analyse whether the period of physical inactivity during COVID influenced the HRQoL and foot pain in these patients with RA.

Table 1

Levels of general pain, foot pain and HRQoL before and after pandemic.

	2018 (before pandemic)	2021 (after pandemic)	Z	effect size	p
SF-12 Physical Component	32.05[26.31–42.77]	35.18[27.28–45.58]	-2.176	-0.20	0.030
SF-12 Mental Component	39.69[29.52–54.70]	34.48[27.09–51.43]	-2.004	-0.18	0.045
VAS general	6[4–7]	7[4–8]	-2.232	-0.20	0.026
VAS foot	5[2–7.75]	7[3.25–8]	-3.285	-0.30	0.001

Data are expressed as median and interquartile range (Me[P25–P75]).

Z: value of the Wilcoxon statistic.

Interpretation: in all 4 cases the size of the effect detected is considered small (approximately when it is < 0.30).

The findings presented in this study show that there is a loss of HRQoL in terms of mental level (34.48[27.09–51.43] $p < 0.05$) and a significant increase in the level of pain, both general (7[4–8] $p < 0.05$) and foot pain (7[3.25–8] $p < 0.001$) in the included patients after the period of physical inactivity during COVID.

Pain is one of the symptoms most reported by patients with RA and has a direct impact on functionality and HRQoL [21]. The results presented in this study corroborate that the mental and physical components are related, and they influence each other. If physical activity decreases, the emotional level worsens. If the patient's depressive state or anxiety increase, the pain also increases. Matcham et al. showed that psychological alterations can distort the interpretation of patients of the symptoms associated with their illness [22].

In 2018 EULAR recommended physical activity and listed the benefits that physical activity brings to patients diagnosed with rheumatic diseases with osteoarticular involvement. In 2020, Azeez et al. also indicated that physical exercise should be protocolized in the management of these rheumatic patients. In addition, it has been shown that sedentary behaviour worsens the symptoms of the disease in general [23].

However, Schouller et al. demonstrated that most of patients with RA prefer to have a sedentary lifestyle [24]. In this regard, the fear of movement that patients with RA suffer can be associated with an increase in pain or even greater joint damage associated with decreased physical activity [25]. This data is important to be highlighted because the COVID-19 period forced a modification to the patient's lifestyle, causing it to be both sedentary and isolated. Also, it changed the social interaction of the general population. Our results agree with the relationship between the physical inactivity and at the level of the detriment in the HRQoL mental component [25].

The HRQoL physical component showed a significant improvement before and after COVID-19, demonstrating that there is not a direct relationship between the HRQoL physical component and physical activity. Unlike the previous studies carried out by Balchin et al. in 2022 and Ramos et al. in 2022, who showed a low level of physical activity in patients with RA [13,26]. It should be noted that this change in physical activity does not imply an improvement in the quality of life at the level of the physical component.

Obesity is highly prevalent in patients with RA [27]. Furthermore, there is a clear association between a higher BMI, foot pain and foot-related activity limitations in patients with RA [28]. However, the results of this study do not show significant relationship between BMI and foot pain in the included participants. The present study shows that there is no direct relationship between high BMI and the increase in foot pain in the population with RA.

4.1. Implications for research and/or practice

Regarding the clinical implications of this research, it shows that periods of physical inactivity make an impact on the HRQoL, especially at the level of the mental component and the perception of generalized pain in patients with RA. This may help clinicians to focus the treatments of these patients on a mental level in situations of isolation or inactivity.

4.2. Strengths and limitations

This study has some limitations, such as the heterogeneity of the sample in terms of gender, because 73.4 % were female. Another limitation was that kinesiophobia was not assessed in the study and this may influence the mental component. On the other hand, this study presents an important strength, because a cohort of participants has been studied for several years. Future studies should include kinesiophobia and the level of activity of the disease.

5. Conclusions

Mental quality of life and pain, both general and foot pain, were influenced by the period of physical inactivity during COVID-19.

Ethical approval

The original article complied with the established ethical principles for human research. This study received ethical approval from the committee of Portal de Ética de la Investigación Biomédica de Andalucía (PEIBA), which was authorized and extended to a longitudinal study ARCO001. This study was carried out in full accordance with the provisions of the Declaration of Helsinki regarding ethical principles for medical research involving human subjects and was approved by the Ethics Committee.

Funding

None.

Competing interests

None.

Acknowledgements

Funding for open access charge: Universidad de Málaga / CBUA.

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