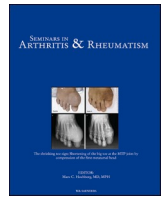


Contents lists available at [ScienceDirect](https://www.sciencedirect.com)

Seminars in Arthritis and Rheumatism

journal homepage: www.elsevier.com/locate/semarthrit

Patient perspectives on long-term outcomes in rheumatoid arthritis. A qualitative study from the OMERACT patient outcomes in longitudinal studies working group

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ARTICLE INFO

Keywords:

Rheumatoid arthritis
Qualitative research
Patient-centered outcomes
Quality of life
OMERACT

ABSTRACT

Objectives: To identify patient-centered domains with long-term relevance to people with rheumatoid arthritis (RA).

Methods: We conducted semi-structured individual cognitive interviews of patients with RA with at least five years of disease duration, sampled from five different countries (United States, Italy, Spain, Mexico, and Argentina). Participants were encouraged to discuss their long-term concerns regarding RA. Interviews were transcribed and analyzed using qualitative content analysis within a constructivist/interpretivist theoretical framework.

Results: Twenty-eight participants were interviewed, 24 were women. Six main themes, representing important aspects of the daily life of people with RA were generated: (i) Living with symptoms and functional limitations, (ii) Lack of participation, (iii) Partner and family issues, (iv) Risk of damage to vital organs, (v) Coping strategies, and (vi) Healthcare concerns, primarily expressed by participants from non-European countries lacking universal healthcare coverage. In addition, participants discussed the importance of contextual factors and how they impact long-term outcomes. These included attitudes towards disease, social support, or financial burdens.

Conclusions: We identified six domains of importance to people with RA that are seldom measured in longitudinal registries and should be considered in patient-centered longitudinal studies.

Introduction

Randomized controlled trials (RCTs) are considered the gold standard to evaluate healthcare interventions. However, they also have limitations, especially when addressing populations with chronic

diseases, such as rheumatoid arthritis (RA). Clinical trials are typically of relatively short duration, and therefore may not capture longer term events or health states. Stringent inclusion and exclusion criteria can result in poor generalizability to real world populations. In addition, it is feasible to compare only a few interventions in an RCT, when many

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<https://doi.org/10.1016/j.semarthrit.2022.152028>

Available online 19 May 2022

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others may be available. For these reasons, there has been increasing interest in using patient registries, and prospective longitudinal observational studies of patients with RA, to add to the evidence from RCTs. While there have been some attempts to standardize the data being collected in registries, primarily in Europe, there have been no efforts to specifically consider patient views with respect to patient-centered long-term outcomes [1–3].

Outcome Measures in Rheumatology (OMERACT) is an international collaboration which aims to improve and standardize outcome measures in RCTs and longitudinal observational studies in rheumatic and musculoskeletal diseases [4]. The current conceptual framework for establishing core sets proposes four core domain areas: death, life impact, resource use/economic impact, and pathophysiological manifestations [4–8]. The initial OMERACT activities for RA resulted in the development of a core set to be used in RCTs [9]. In 2016, we established the Patient Outcomes in Longitudinal Studies (POLOS) Special Interest Group with the goal of identifying domains of importance to people with a rheumatic and musculoskeletal diseases that should be considered in patient-centered prospective longitudinal observational studies [10–12]. An initial systematic review of international registries and observational studies of people with RA showed high heterogeneity of collected variables [13]. Physical function and pain were the most commonly collected patient centered outcomes. It was therefore felt that additional research was needed to better understand the perspectives of people living with RA [14]. We conducted an international qualitative study seeking the views of people with RA across five countries to ascertain their views with respect to patient-centered domains that they perceive could impact their long-term wellbeing.

Methods

We report our results following the Journal Article Reporting Standards for Qualitative primary research (JARS-Qual) [15] and the COnsolidated criteria for Reporting Qualitative studies (COREQ) [16]. The study was evaluated and approved by the Research Ethics Committees of the *Universidad de Alcalá de Henares* (CEID/HU/2018/30) and by the institutional research boards of each participating institution.

Research team

Our research team comprised clinical researchers with expertise in qualitative research (JB, LC, MLO, MSA), rheumatology (FI, NZ, JIGN, LGL, VS, LM, MLO, NG, MSA, LC) and clinical epidemiology (MLO, RC, MSA, VS, LC), with doctorate level training in their areas of expertise. Two researchers were patient representatives (NG, TWR).

Research design

Theoretical framework. We conducted a qualitative study using individual structured interviews with an experiential research approach in which we validate the meanings, views, perspectives, experiences, and/or practices expressed in the data. This type of research focused on meaning and experience, what people think, do, and feel, and how they make sense of their realities [17]. For this work our ontological and epistemological assumptions stand by the constructivist/interpretivist paradigm which establishes: (i) that there are multiple subjective realities, each of which is socially constructed by and between individuals, and (ii) that knowledge is subjective and formed at an individual level [18].

In addition, an interview guide was developed covering the following topics: overall life impact, symptoms and physical function, social function and participation, work and related activities, financial status, psychological wellbeing, and therapy-related issues (Supplementary Table 1). The interview was adapted by the interviewers as needed to foster a comfortable environment for the interviewees if unexpected topics emerged.

Participant selection. Participants were recruited from five different countries (United States, Mexico, Spain, Argentina, and Italy) and selected through purposeful sampling; this type of sampling aims to reflect the diversity within the group or population being studied, rather than aspiring to only select a representative sample, also allowing for the identification of information-rich cases [19]. We included individuals with RA of at least five years duration as we wanted participants with the experience of having lived with RA for a period that would have given them the experience and knowledge of living with this chronic disease. This was important to the research team, as the purpose of the study was to identify patient-centered domains that would be relevant for long-term wellbeing of patients.

Setting. Interviews were conducted in person, by phone or video-conference in 2018 and 2019. Participants were recruited through invitation by their rheumatologists, who were informed about the study. All gave consent to participate in the interviews.

Data collection. For each country a researcher was responsible for recruiting and interviewing the participants, audio recording the interviews, and performing *verbatim* transcription of the recordings. Italian interviews were translated to English. Spanish and English interviews were analyzed in the original language. Final transcriptions were sent to the first author, expert in qualitative research methodology, who performed the data analysis and interpretation. For publication purposes, the direct quotations in Spanish that are part of the results were subsequently translated into English.

Data analysis

The transcriptions underwent a quality assessment assisted by Express Scribe Transcription Software Pro (v 7.03 © NCH Software), by comparing each transcription with its respective audio-recorded interview [20]. From the quality assessment, data about the social context initially omitted in some of the transcriptions were included (e.g., tone of speech, laughing, or crying). In addition, asynchronous communication and meetings with the multilingual researchers helped to clarify context-dependent meaning.

Data were analyzed using qualitative content analysis assisted by ATLAS.ti (GmbH, Berlin, v. 8) software. The goal was to identify patterns in people's experiences of living with RA. The content analysis was divided into the following phases: building a coding frame, segmentation, pilot phase, main analysis and interpretation [21, 22]. The coding frame was developed by a combination of concept-driven (using the interview guide) and data-driven techniques [23]. For the segmentation, a thematic criterion was used. Once the coding frame was developed, the methodologist tested it on part of the material (one interview of each country) during two rounds of coding within 12 days [22]. From the pilot phase, few changes were made to the coding frame which was then applied to the entire data set. After the coding was finished by the qualitative research methodologist, the process was fully reviewed by three additional researchers with experience in patient-centered outcomes research.

Results

A total of 28 interviews were conducted of which 21 were face to face, two over the phone and five by videoconference. The duration was approximately 75 minutes. Table 1 shows the characteristics of the participants.

Six main themes were generated: (i) Living with symptoms and functional limitations - encompassing any physical or psychological symptoms, (ii) Lack of participation - activities related to social or work participation, (iii) Partner and family issues - problems or need for adaptation in close relationships and sex life, (iv) Risk of damage to vital organs - any perceived risk to organs caused by RA or its treatment, (v) Coping strategies - techniques and practices to help reduce the discomfort caused by the disease, and (vi) Healthcare concerns - present

Table 1
Participants characteristics (n = 28).

Country	n	Women	Median age (min, max)	Median disease duration in years (min, max)	Education level (College)	Married or living with partner
Argentina	6	5	62 (48, 78)	24 (20, 40)	0	3
Italy	5	4	59.5 (31, 90)	15 (7, 18)	1	3
Mexico	9	8	61 (42, 92)	18 (8, 60)	0	4
Spain	4	3	48 (45, 58)	27 (10, 40)	2	3
United States	4	4	60 (55, 71)	8 (6, 19)	4	3
Total:	28	24 (85.7%)	60 (31, 92)	18.5 (6, 60)	5 (17.9%)	16 (57.1%)

or future concerns related to healthcare. Table 2 presents direct quotations from participants by main themes.

Theme one: Living with symptoms and functional limitations

Physical. The most emphasized symptoms were stiffness, lack of energy, and joint pain, highlighting how these symptoms affected interviewees' basic daily activities such as eating or taking care of their hygiene.

Psychological. Emotional symptoms such as sadness, anxiety, loneliness, pessimism, hopelessness, irritability, and shame were often mentioned as limiting by participants. Specific fears of adverse events from prescribed drugs as well as death, either from the disease or from side effects, were also expressed.

Theme two: Lack of participation

Social context. Isolation and difficulties in partaking in social life were commonly mentioned by participants to be a direct consequence of their disease. However, some participants mentioned that they were able to adjust their social participation to their new reality. Participants who expressed having support from family and/or friends who understood the disease mentioned that they were able to adjust to their new reality. Those participants who felt isolated from social life perceived that loss of autonomy and a lack of empathy by friends and family members as major contributors to their isolation. People who felt isolated expressed more psychological symptoms and discomfort. In contrast, people who were able to participate in social life were more comfortable with their disease.

Work context. More than half of the participants had to stop working due to their disease. The type and characteristics of their work duties were considered important with respect to their ability to continue working. Some patients reported being laid off or forced to resign because of work absences. Some also reported that they stopped working because their work duties could not be tailored to their needs. Participants felt that their ability to perform their work duties was related to the severity of their symptoms. However, most participants highlighted the emotional and physical benefits of maintaining their jobs, especially when their duties could be adapted to their disease limitations.

Theme three: Partner and family issues

Intimacy. Intimacy is defined as a relation of closeness with another person, often associated with emotional elements such as trust and complicity. Participants often signaled relationship issues due to poor communication, emotional burden, or lack of empathy. Older

Table 2
Direct quotations from participants by main themes

Theme		Data extracts
Living with symptoms and functional limitations	<i>Physical</i>	"...joint pain is latent, and I manage it, I pretend that there is no pain at all, and I do everything but, in some periods, I feel the discomfort. In other periods, like today I feel stiffness." "I had (sometimes) difficulties in getting up the blinds in the morning and making the movements to wear my pants, and I had to ask for help." "It is difficult even to eat. The other days I went to a restaurant, and the waitress had to help me cut my own food." "I cannot even wipe my ass when I go to the restroom. I need help from my husband."
	<i>Psychological</i>	"It has a great impact on my self-perception. The changes in my body changed me as a person. I used to be outgoing, now I am not outgoing. You try to be normal, but you cannot, and that gives me anxiety." "It's a rise and fall of emotions every day, but sadness is more or less always present." "I do not value myself, with the time it got worse...the complexity of the disease slowly destroys you. It is frustrating when you tried to do something, and you failed." "When I got angry with the disease, I try to stop my thoughts and tell myself: I am alive, I have eyes, I can walk with difficulty but hey I can walk. I am alive."
Lack of participation	<i>Social context</i>	"I tend to schedule less and do less. I am very careful of what I offer to do because I do not know if I am going to be able to do all of it." "My friends support me; they are always looking for activities in which I can participate." "I cannot take dance or yoga classes anymore." "I do not have a social life. The only social life I have is the doctor office and home."
	<i>Work context</i>	"I received a disability, I cannot type or even climbing stairs. It is sad because work gives your mind something to focus outside the disease." "I used to work in domestic labor but when the disease appear my employer told me that I should consider quitting. The disease symptoms were interfering with my work tasks." "I still work and in part thanks to my boss. He was very supportive. My tasks were adapted to my condition." "I would say that arthritis has pushed me to look for a job with a strong flexibility that allows me to ensure that arthritis does not become a problem."
Partner and family issues	<i>Intimacy</i>	"At first, my relationship with my husband was affected. However, we found a way to understand the disease together and now we are closer than ever." "I know that is hard to live with

(continued on next page)

Table 2 (continued)

Theme	Data extracts
	<p>someone with a chronic condition but sometimes I do not feel understood. I wish we can communicate better.”</p> <p>“We do not have sex, because we are very old, but we always sleep together. That keeps us closer to each other.”</p> <p>“At our age, sex is different and with the disease it has evolved over time but it is always good to feel that you have someone there who supports you and love you.”</p>
<i>Sexual activity (frequency and quality)</i>	<p>“Sex is obviously affected but nobody tells you anything about this. Rheumatologists think we do not fuck, and oh my they are so wrong.”</p> <p>“We still have sex but with some adaptations and ground rules that may vary depending in how my body is responding that day.”</p> <p>“The vaginal dryness occasioned by the diseases is very painful. However, we found new ways to give us pleasure. The disease pushed us to reinvent our sexual repertoire.”</p> <p>“I have been sexually inactive for a few years. The lack of mobility is very uncomfortable.”</p>
<i>Fertility and raising a family</i>	<p>“Becoming a mother was very difficult and painful process.”</p> <p>“With the medications and the disease, having a baby was difficult. I try it once, but it ended in a miscarriage”</p> <p>“I am concerned to be unable to be there for my daughter when she needs me most.”</p> <p>“Medicine is not perfect, and I am sure that all the medication that I am taking might have unknown secondary effects that are shortening my life. I am scared, very scared to die young and leave my son an orphan.”</p>
<i>Risk of damage to vital organs</i>	<p>“I am concerned about my kidneys and liver. More specific medicines oriented to the disease should be developed.”</p> <p>“I have recurrent respiratory infections. My lungs are affected, and I know it is because the exposure to the medication. I am worried about it.”</p> <p>“I am very concerned about getting cancer and possible brain damage as an effect of using the medication for so long.”</p> <p>“Heart disease. Heart failures are my major concern. The medication helps with the symptoms of the RA, but I am afraid that it is affecting my heart.”</p>
<i>Coping strategies</i>	<p>“At the beginning it was hard but then I started seeing the disease as close friend. She goes with me everywhere.”</p> <p>“I always try to go to Church. I feel better when I go, it gives me power.”</p> <p>“I pray to God and ask him for strength to continue with my life despite the disease.”</p>

Table 2 (continued)

Theme	Data extracts
	<p><i>Learned</i></p> <p>“You need to be able to laugh in face of adversity. If I lose my sense of humor, what do I have left?”</p> <p>“I am very selective with the plans I schedule. I say no more often, because I need and respect my rest time.”</p> <p>“Well basically my right hand is very affected, so I trained myself to use my left hand.”</p> <p>“I adapted some of my hobbies. They help me by keeping my mind busy.”</p> <p>“I try to go out with my friends at least two times a month. Outdoor activities help me to focus on the good things I still have.”</p>
<i>Healthcare concerns</i>	<p><i>Financial burden</i></p> <p>“We have a good health coverage, but I am always concerned if I am able to cover all the deductibles.”</p> <p>“I am hoping to find something that gives me relief, so I can go back to work in order to be able to gain money for my medical expenses.”</p> <p>“I am always looking at the news about possible changes in Medicare and Medicaid because they can affect my actual coverage.”</p> <p>“Sometimes it is very hard to pay the bills on time because the medical appointments and medication are very expensive.”</p> <p>“I received all I need from the national health insurance. The appointments and medication are not a concern.”</p> <p>“All my medications are covered by the national insurance.”</p> <p>“My treatment is fully covered by the national insurance. We are very lucky; I cannot imagine how the people in the U.S. manage their disease. That is a complete madness, people health should not be a business.”</p> <p>“We have a code for RA, and with this code you don’t pay many drugs and exams. Even if you have to pay some exams, their costs are not significant.”</p>

participants reported more issues with intimacy than younger ones.

Sexual activity. Limitations specifically in sex frequency and sex quality, were expressed more frequently by younger patients. Lack of mobility and disease symptoms, combined with adverse effects of prescribed drugs, hindered sexual activity. Some participants reported having given up on their sexual life.

Fertility and raising a family. Women mentioned fertility as an important aspect affected by the secondary effects of medications. Concerns related to raising a family were mentioned by both men and women. Participants expressed difficulties related to taking care of a child, either their own or their grandchildren. Those who self-identified as mothers and fathers also expressed fear of a premature death and/or of passing the disease into offspring. Some mentioned their children gave them a reason to continue living.

Theme four: Risk of damage to vital organs

Drugs related. Participants were concerned about the disease or its treatment damaging vital organs; the organs mentioned most frequently

were kidney, liver, lungs, heart, and brain. They were also concerned about acquiring other conditions (e.g., cancer, infections) or developing systemic complications of their RA such as vasculitis. Some were worried of becoming resistant to their drug therapies.

Theme five: Coping strategies

Participants identified various coping strategies and behaviors that they considered useful to manage their disease. We categorized these into inherent (primarily personality traits) and learned (skills and attitudes that can be acquired).

Inherent. Religion and spirituality were perceived as meaningful to cope with the disease adversities. Participants also identified optimism as crucial in managing their illness and valued having a sense of humor. Receptivity, as in being open to try a new experience or being receptive to a new idea, was considered beneficial.

Learned. Learned behaviors such as resting when needed, learning how to say no, and engaging in pleasant activities to distract the mind were considered useful coping strategies. In addition, good impulse control and goal-directed behaviors such as “trying to do well the thing that I should do” were highlighted.

Theme six: Healthcare concerns

Financial burden. The high cost of medications and medical care was a major source of concern among participants in countries without universal national health systems such as the United States, Mexico, and Argentina. These financial burdens also resulted in barriers to engage in beneficial health behaviors such as following healthy lifestyle recommendations or adherence to treatment.

Discussion

Our study revealed important aspects of the daily life of people with long-term RA that are affected by their disease. Symptoms and physical function are often evaluated in clinical studies and are partially included in the OMERACT RA core set of domains for RCTs [24]. However, it is important to highlight that several themes and subthemes identified by people with RA as important are not systematically included in RCTs other than as broader constructs, such as quality of life. The other five dominant themes in our study included lack of participation (social and work-related), partner and family issues, risk of damaging vital organs, coping strategies, and healthcare access concerns. The degree of granularity of psychological aspects that were deemed important to people with RA in the long-term highlights the need to study these domains in depth in longitudinal observational studies.

Difficulties in participation in social and work activities was associated with two clearly distinct psychological attitudes and consequent behaviors: isolation or adaptation. Individual emotional constructs, type of work and adaptability, and the quality of support within the patient’s close social environment were identified as modulators or contextual factors. Participants expressed the importance of work maintenance, and the need for work adaptation to the new reality of the disease. Prior studies have reported the effects of maintaining work in people with RA [25, 26]; and the European Alliance of Associations for Rheumatology (EULAR) has established maintaining people at work as a strategic priority, illustrated by the Edgar Stene Prize Competition “My ideal employer – Work without barriers for people with rheumatic and musculoskeletal diseases” [27], events at the European Parliament [28], and the Time2Work campaign [29].

Regarding partner and family issues we found that intimacy and sex life—despite the growing body of evidence [30–34]—remain unaddressed topics even if important for people with RA. As expressed by one participant, “most rheumatologists do not assess it in their clinical practice”. As a result, the person with RA faces unexpected barriers for which he or she might not have the necessary tools to deal with their

concerns. The age of the affected person was an important factor in this theme. Older participants were more concerned with intimacy issues in contrast to younger participants who were more concerned with frequency and quality of sexual activities. However, both aspects are not mutually exclusive, and should be further explored in patients with RA of all ages, as they clearly impact wellbeing.

Women expressed their concerns about fertility being affected by the disease or its treatment. Their experiences align with prior research showing that infertility in women with RA although frequent, is often under-recognized [35]. With respect to raising a family, participants of both sexes frequently mentioned their fear of being unable to care for their dependents, not only because of their disease but also because of the possibility of a premature death related to complications of the disease.

Fear of possible damage to vital organs was highlighted by several participants. They perceived medication used over time as a threat to their health because of the possible damaging effects to their kidneys, liver, lungs, heart, and brain. Interestingly, the kidney was an organ of major concern [13]. While these complications and concomitant comorbidities are well recognized in clinical studies, they are not usually systematically measured in long-term cohort studies of people with RA.

Participants identified coping strategies useful in the management of their disease. Some were considered as inherent to the individual and others as potentially learned. Optimism and developing a healthy sense of humor were the most frequent coping strategies mentioned. There is increasing interest in how coping may improve outcomes in RA [36, 37]. Healthy coping strategies are a useful tool for the management of the disease [38, 39].

The experience of living with long-term RA was generally similar among participants from different countries. However, as healthcare systems differ across countries, some responses emerged as clear contextual factors of outcomes and concerns. Participants from Italy or Spain, both countries with universal health coverage, did not express major concerns regarding financial burdens related to the costs of healthcare in contrast to participants from the other countries who expressed latent uncertainty about their access to adequate health care and its associated costs. This highlights the importance of considering contextual variables of interest that may vary across countries in international studies.

Overall, while some of the themes discussed by participants referred to long-term outcomes (e.g., functional domains), others are probably better defined as contextual factors, e.g., social support, healthcare access. In research, contextual variables are factors (study characteristics) that without being outcomes *per se*, can impact outcome domains, and therefore, need to be recognized to fully understand the impact of a disease [40, 41].

A limitation of our study was the predominance of women among the participants. While it is true that RA affects more women than men, future studies should examine potential variations according to gender. Also, our results were primarily coded by one researcher, but all transcripts and coding were subsequently reviewed independently by an additional researcher for consistency and interpretability.

In summary, our study generated essential insights grounded to the reality of people living with RA. We generated six main themes that were important to patients, but these are seldom included in RCTs and prospective cohort studies. Our findings indicate the need to measure various patient-centered outcomes and outcome influencing contextual factors in long-term longitudinal observational studies to better capture the complexities of living with RA.

Disclosures

LC has not received fees or personal grants from any pharmaceutical companies, but her Institute performs contract work for pharmaceutical companies including Abbvie Spain, Eisai, Gebro Pharma, Merck Sharp & Dohme España, S.A., Novartis Farmaceutica, Pfizer, Roche Farma,

Sanofi Aventis, Astellas Pharma, Actelion Pharmaceuticals España, Grünenthal GmbH, and UCB Pharma.

VS is a founder and member of the executive of OMERACT [1992 – present], an organization that develops and validates outcome measures in rheumatology randomized controlled trials and longitudinal observational studies and receives arms-length funding from as many as 36 sponsors.

NG is Chief Medical Officer at Abcure, Inc

MSA has received consultant honoraria from Gilead, Avenue Therapeutics, ChemoCentryx and Pfizer. Current consultant for Celgene. All activities unrelated to this work

Acknowledgements

We would like to express our gratitude to the study participants who shared their experiences and beliefs to help us better understand their journey through life with RA. We are grateful as will to all the participants in OMERACT, especially in the POLOS Significant Interest Group who encouraged us to pursue this work. Section for Biostatistics and Evidence-Based Research, the Parker Institute, Bispebjerg and Frederiksberg Hospital is supported by a core grant from the Oak Foundation (OCAY-18-774-OFIL).

Financial support

JBN has received personal grants from the European Alliance of Associations for Rheumatology (EULAR) for activities unrelated to this work.

MALO is supported by a career award from the National Cancer Institute (K08CA237619).

Supported in part by the National Institutes of Health through MD Anderson's Cancer Center Support Grant (CA016672). The Parker Institute, Bispebjerg and Frederiksberg Hospital are supported by a core grant from the Oak Foundation (OCAY-18-774-OFIL).

Supplementary materials

Supplementary material associated with this article can be found, in the online version, at [doi:10.1016/j.semarthrit.2022.152028](https://doi.org/10.1016/j.semarthrit.2022.152028).

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