

## Original article

**Quality of life and unmet needs in patients with inflammatory arthropathies: results from the multicentre, observational RAPSODIA study****Roberto Giacomelli<sup>1</sup>, Roberto Gorla<sup>2</sup>, Francesco Trotta<sup>3</sup>, Rosella Tirri<sup>4</sup>, Walter Grassi<sup>5</sup>, Laura Bazzichi<sup>6</sup>, Mauro Galeazzi<sup>7</sup>, Marco Matucci-Cerinic<sup>8</sup>, Raffaele Scarpa<sup>9</sup>, Fabrizio Cantini<sup>10</sup>, Roberto Gerli<sup>11</sup>, Giovanni Lapadula<sup>12</sup>, Luigi Sinigaglia<sup>13</sup>, Gianfranco Ferraccioli<sup>14</sup>, Ignazio Olivieri<sup>15</sup>, Piero Ruscitti<sup>1</sup> and Piercarlo Sarzi-Puttini<sup>16</sup>****Abstract****Objective.** The observational RAPSODIA (RA, PsA and spondylitis including AS) study was planned to assess, in patients with RA, AS and PsA, their involvement in medical decisions, quality of life and unmet needs 15 years after the introduction of biologic therapies in Italy.**Methods.** Patients completed a questionnaire during their scheduled rheumatology consultation. They rated their satisfaction with disease knowledge on a 5-point scale (1 = not at all satisfied, 5 = totally satisfied). Self-efficacy, defined as judgement of one's own ability to achieve given levels of performance and exercise control over events, was measured using the pain subscale of the Arthritis Self-Efficacy Scale. Patients' global assessments of pain, fatigue and disease activity were recorded on 100 mm visual analogue scales (0 = best status, 100 = worse status). Disease activity status was assessed using standard tools. Health status was measured using the 36-item Short Form Health Survey and the Italian version of the HAQ.**Results.** Ninety-eight per cent of patients reported that their health care practitioner used understandable terms to explain their condition. Joint issues and general symptoms (e.g. fatigue and malaise) were common. All measures of disease activity and self-efficacy scores were markedly better in patients receiving biologic vs conventional therapy. Biologic therapy recipients were more productive at work.**Conclusion.** These results confirm that some patients with rheumatic diseases are not satisfied with the level of information they receive about their treatments. Biologic therapy appears to be an important advance, with patients receiving this form of treatment having improved symptoms and productivity. However, patients still report unmet needs. Thus further research, and perhaps new and more effective therapies, along with better education and multidisciplinary collaboration, are required to improve outcomes.**Key words:** rheumatoid arthritis, ankylosing spondylitis, psoriatic arthritis, quality of life, productivity, unmet needs, biologic therapy, patient education.

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## Introduction

Over the last decade patients have been encouraged to take an active role in decision making about their care in order to improve their clinical outcomes. To be involved in this active decision-making process, patients need to be informed about their disease and treatment options. At present, widespread access to medical information via the Internet makes it easier for patients, including patients with rheumatic diseases, to obtain information [1].

RA, PsA and AS have a chronic course, require lifelong management and have a negative impact on quality of life. Recent data show that involving these patients in shared decision making improves their outcomes, although RA patients show significant gaps in disease knowledge [2–4].

Improving work ability and maintaining overall quality of life are important steps in rheumatic disease management, together with controlling inflammation, alleviating stiffness and pain and preventing joint deformity. Early intervention significantly reduces the impact of chronic inflammation and facilitates achievement of clinical remission, although the remission rates remain suboptimal and radiographic progression occurs in about half of all RA patients [1–4].

Satisfaction of RA patients with their care includes trust in the physician and the professional health care staff. Furthermore, asking patients to identify unmet needs facilitates the delivery of quality health care. On the other hand, dissatisfaction with care is more common in patients who describe unmet health care needs, which may be specific to different health care settings, making generalizability difficult [1–6].

The observational RAPSODIA (RA, PsA and spondylitis including AS) study was designed to evaluate the quality of life and unmet needs in patients with RA, PsA or AS in Italy. The aims were (i) to assess information delivery to patients, (ii) to assess patient involvement in medical decisions and (iii) to determine unmet health care needs and how these relate to health status.

## Methods

### Study population

The multicentre RAPSODIA study was conducted at 16 sites in Italy. Patients were included if they were >18 years of age, had a diagnosis of RA, PsA or AS based on standard criteria [7–9], had been receiving rheumatology care for the previous 2 years and were able to read and understand the Italian language. Patients were classified into two groups: those receiving biologic therapy (biologic treated) and those treated with conventional therapy but eligible for biologic therapy because of inadequate or lack of response (biologic eligible). The study was approved by the local ethics committees, informed consent was obtained from all patients prior to enrolment and the study was conducted in accordance with good clinical practice and the principles of the Declaration of Helsinki.

### Data collection

Patients were asked to complete, anonymously and independently, a specifically developed questionnaire during their scheduled rheumatology consultation. There were 60 questions in 14 domains, including quality of life, time of diagnosis, waiting time for appointments, disease awareness, employment status, sources of information about the disease, impact of both disease and therapy on quality of life, participation in medical decision making and level of satisfaction with their current anti-rheumatic therapies and standard of care. Patients were also asked about satisfaction with their knowledge of their disease on a 5-point scale (1 = not at all satisfied, 5 = totally satisfied).

Self-efficacy, defined as judgement of one's own ability to execute given levels of performance and exercise control over events [10], was measured using the pain subscale of the Arthritis Self-Efficacy Scale [11]. Patients' global assessments of pain, fatigue and disease activity were recorded on 100 mm visual analogue scales, with scores ranging from 0 (no pain, fatigue or disease activity) to 100 (highest levels of pain, fatigue or disease activity). Disease activity status was assessed using the 28-joint DAS (DAS28) [12] for RA and the BASDAI [13] for AS and PsA. The patients' current functional status was assessed using the BASFI [14] for AS and PsA. Health status was measured using the Medical Outcomes Study 36-item Short Form Health Survey (SF-36) [15, 16] and the Italian version of the HAQ [17]. Age and disease duration were measured in years; sex, marital status, employment status and the presence of co-morbidity were recorded as dichotomous variables.

### Statistical analysis

Data were evaluated using parametric and non-parametric analysis. Continuous and ordinal data are presented as median (range) and categorical data are shown as absolute count and percentage. The unpaired Mann-Whitney *U* test was used for between-group comparisons where appropriate and Pearson's and Spearman's correlation coefficients were calculated where indicated. The statistical significance level was set at  $P = 0.01$ .

## Results

### Patients

A total of 743 patients were enrolled in the study. Fifty-eight per cent were female, 42% were male, 250 patients were 18–45 years of age and 493 were >45 years of age. The inflammatory arthropathy was RA in 327 patients, PsA in 214 patients and AS in 200 patients.

### Diagnosis

There was an average 4-year delay between the onset of disease symptoms and diagnosis, independent of the type of inflammatory arthropathy. Patients consulted a variety of different health care professionals at symptom onset, usually their primary care practitioner. However, the diagnosis of RA, PsA or AS was almost exclusively done by a rheumatologist.

### Understanding of disease, information and involvement

The majority of patients (98%) reported that their general practitioners explained their disease in understandable terms. The other main sources of information used by patients were the Internet, television and newspapers. About 60% of enrolled patients needed more information, especially about diagnosis, medication, exercises and how to improve performance of daily activities, and only about one-third (37.1%) were satisfied with the information provided during treatment. Fifty-one per cent of patients reported good involvement in the process, with no difference between the various diseases. Self-efficacy scores were consistently higher in biologic-treated patients compared with those who were biologic eligible [RA biologic-eligible patients 38.4 (range 10–100) vs RA biologic-treated patients 69.5 (range 10–100),  $P < 0.01$ ; PsA biologic-eligible patients 36.9 (range 10–100) vs PsA biologic-treated patients 67.6 (range 10–100),  $P < 0.01$ ; AS biologic-eligible patients 37 (range 10–100) vs AS biologic-treated patients 78.9 (range 10–100),  $P < 0.01$ ].

### Symptoms, quality of life and work productivity

We identified the role of various symptoms in terms of their impact on quality of life and their frequency is shown in Table 1. Fatigue and malaise affected about 50% of patients. Other symptoms were tender and swollen joints (52%), reduced joint mobility (26%), back pain (26%), walking difficulties (22%) and morning stiffness (19%). Biologic-eligible patients experienced a significantly higher average level of pain.

Although 97% of patients were in agreement with their physicians about disease management, 72% felt that their life was ruled by the disease and expressed frustration about their disability. More than 60% were no longer able to carry out normal activities, which strongly affected their psychological well-being. In fact, anxiety was reported by 57% of patients, 39% showed levels of irritability and 21% reported sexual problems. Furthermore, work performance was often impaired: employed patients lost an average of 6 working days during the 3 months prior to completion of the questionnaire, associated with an average 9.3% reduction in income. Overall, 34% of the patients reported difficulties at work, 11% had increased work absenteeism and 7.9% retired from their job.

### Therapy

Of the biologic-treated patients, 51% received adequate information and participated in the therapy decision. Furthermore, patients complied better with simplified therapeutic regimens, and 69% of patients preferred monthly s.c. therapy if efficacy was maintained.

Ninety-seven per cent considered the importance of therapy for disease control. However, several disadvantages were highlighted, related to injections, which were the cause of malaise in 19% of patients, pain in 20% and local irritation in 26%. It should be noted that satisfaction with biologic therapies was higher than for conventional treatments, paralleling the DAS in biologic-treated

patients compared with those who were biologic eligible (Table 2).

Seventy-five per cent of biologic-treated patients reported that their work performance increased during treatment. The proportion of patients rating therapy as being able to strongly ameliorate symptoms was 66% in those who were biologic eligible and 94% among those who were biologic treated. About the perceptions of biologic therapy, 97% of patients thought that biologics slowed disease progression, 96% thought these agents slowed the progression of joint deformity, 95% thought they provided long-term relief, 93% said they had fewer relapses and 91% reported a reduction in pain and swollen joints.

## Discussion

Nearly all of the patients in this study reported that their health care practitioner used understandable terms to explain their condition. A somewhat lower percentage was satisfied with the information provided by their physician. Data also showed that joint issues were common, as well as fatigue and malaise. Both disease activity and self-efficacy scores were significantly better in biologic-treated patients, and biologic therapies improved the patients' work ability.

A significant delay in diagnosis was observed, suggesting that general practitioners need to identify potential rheumatic patients as soon as possible and promptly refer them to a specialist [2]. In Italy, many early arthritis clinics have been established to evaluate patients in the early stages of the disease, allowing intervention with disease-modifying therapies. The main symptoms observed were fatigue and malaise, tender and swollen joints, reduced joint mobility, back pain, walking difficulties and morning stiffness, mirroring those reported in previous studies [1].

Education is one of the cornerstones of care in rheumatic patients. Overall, nearly two-thirds of patients were satisfied with the information provided by their physician, confirming previously reported rates (68%). However, provision of information to patients with chronic diseases such as RA, PsA and AS is not a simple or static process, and information evolves over time [4–6]. Our data showed that the main sources of information used by patients were the Internet, television and newspapers, although many patients were not satisfied with the level of information they had.

Just over half of all patients (51%) stated that they had good involvement in the process, with no difference between the different diseases. A patient-focused approach based on the participation of patients in medical decision making is associated with improved outcomes [6]. Furthermore, patients who are satisfied and involved in their care are more compliant with treatment and experience fewer adverse outcomes [4]. Among biologic-treated patients, 51% received adequate information and shared decisions about therapy. Data show that patients comply better with less complex therapeutic regimens and that 69% of patients would prefer monthly s.c. therapy if efficacy is maintained.

**TABLE 1** Frequency of commonly reported symptoms in patients with RA, PsA or AS, overall and stratified by the use of biologic therapy

N (%)	RA (n = 327)		PsA (n = 214)		AS (n = 200)	
	Biologic treated (n = 220)	Biologic eligible (n = 107)	Biologic treated (n = 147)	Biologic eligible (n = 67)	Biologic treated (n = 152)	Biologic eligible (n = 48)
Pain/swelling in hand/foot joint	444 (59.9)	97 (90.7)	80 (54.4)	54 (80.6)	44 (28.9)	19 (39.6)
Pain in different joint	333 (44.9)	67 (62.6)	56 (38.1)	37 (55.2)	64 (42.1)	22 (45.8)
Lumbar pain	330 (44.5)	46 (43.0)	52 (35.4)	36 (53.7)	82 (53.9)	40 (83.3)
Cervical pain	332 (44.8)	59 (55.1)	59 (40.1)	31 (46.3)	74 (48.7)	32 (66.7)
Reduction of joint movement	440 (59.4)	86 (80.4)	71 (48.3)	49 (73.1)	83 (54.6)	33 (68.8)
Joint stiffness on waking up	443 (59.8)	86 (80.4)	78 (53.1)	50 (74.6)	80 (52.6)	40 (83.3)
Limited dexterity	477 (64.4)	80 (74.8)	88 (59.9)	47 (70.1)	85 (55.9)	42 (87.5)
Difficulty in taking or gripping/squeezing something	376 (50.7)	88 (82.2)	65 (44.2)	38 (56.7)	35 (23.0)	19 (39.6)
Limited ability for daily activities	357 (48.2)	69 (64.5)	56 (38.1)	39 (58.2)	54 (35.5)	30 (62.5)
Difficulty walking	330 (44.5)	64 (59.8)	56 (38.1)	38 (56.7)	47 (30.9)	26 (54.2)
Decreased ability in leisure activities	377 (50.9)	60 (56.1)	68 (46.3)	36 (53.7)	72 (47.4)	36 (75.0)
Difficulty sleeping	270 (36.4)	56 (52.3)	42 (28.6)	33 (49.3)	47 (30.9)	23 (47.9)
Fatigue	463 (62.5)	82 (76.6)	87 (59.2)	49 (73.1)	88 (57.9)	31 (64.6)
Weakness	335 (45.2)	68 (63.6)	57 (38.8)	33 (49.3)	61 (40.1)	22 (45.8)
Malaise	240 (32.4)	51 (47.7)	36 (24.5)	26 (38.8)	39 (25.7)	21 (43.8)
Fever	26 (3.5)	5 (4.7)	2 (1.4)	5 (7.5)	4 (2.6)	4 (8.3)

All values are given as n (%).

**TABLE 2** DASs in patients with RA, PsA or AS, according to their biologic therapy

Score	Biologic eligible, median (range)	Biologic treated, median (range)	P-value for between-group comparison <sup>a</sup>
RA patients			
DAS28	5.1 (3.9–6.2)	2.9 (2.4–3.5)	<0.01
HAQ	2.3 (0.5–2.8)	0.8 (0–2.3)	<0.01
SF-36			
Physical function	45 (0–97)	72.5 (0–100)	<0.01
Role physical	20 (0–100)	78.5 (0–100)	<0.01
Bodily pain	25.2 (0–98)	64 (20–100)	<0.01
Vitality	33.3 (0–85)	65.2 (0–93)	<0.01
General health	39.5 (0–92)	45.5 (12–89)	<0.01
Social function	48.2 (0–100)	90.2 (10–100)	<0.01
Mental health	58.2 (0–94)	70.2 (22–100)	<0.01
Role emotional	32.4 (0–100)	90 (0–100)	<0.01
PsA and AS patients			
BASDAI	68.71 (58.24–72.28)	39.24 (35.11–43.56)	<0.001
BASFI	66.9 (10.2–95.3)	27.6 (0–85.2)	<0.001
SF-36			
Physical function	47 (0–93)	78.9 (0–98)	<0.001
Role physical	29.4 (0–92)	87.8 (0–100)	<0.001
Bodily pain	22.5 (0–100)	75 (18–100)	<0.001
Vitality	30.4 (0–81)	72 (0–100)	<0.001
General health	34.5 (0–98)	55.2 (15–95)	<0.001
Social function	47.9 (0–100)	91.3 (17–92)	<0.001
Mental health	56.2 (0–98)	69.2 (30–100)	<0.001
Role emotional	35 (0–100)	90 (0–100)	<0.001

<sup>a</sup>Mann-Whitney *U*-test; SF-36: Medical Outcomes Study 36-item Short Form Health Survey.

Self-efficacy scores were consistently higher in biologic-treated patients when compared with those who were biologic eligible, the latter showing a significantly higher average level of pain. Satisfaction with biologic therapies was higher than for conventional treatments, supporting current trends of earlier initiation of biologic therapies in rheumatic diseases [1–6].

The ability to maintain work productivity is an important issue for patients with rheumatic diseases. Three-quarters of our biologic-treated patients increased their work performance, mirroring the results from two large trials in patients receiving either adalimumab or etanercept [18, 19].

It is important to note that the cross-sectional design of this study does not allow any inference of associations to be made. Also, the questionnaire used was designed specifically for this study, limiting the generalizability of the data obtained. It also needs to be pointed out that the patients surveyed in this study were recruited from secondary care clinics. Nevertheless, these data provide useful information on issues for patients with rheumatic diseases in the Italian health care setting, supporting previous data that compared two different health care systems (Spanish vs Brazilian) in which larger investment in the Spanish health care system provides higher quality of life and better outcome in rheumatic patients [20].

In conclusion, the results of the RAPSODIA study show that some Italian rheumatic patients are still not fully satisfied with the level of information they receive about their

treatments and confirm that biologics may improve symptoms and productivity in rheumatic patients. Further research and new and more effective therapies, along with better education and multidisciplinary collaboration, are required to improve outcomes in these patients.

#### Rheumatology key messages

- Collaborative care improves outcomes in patients with rheumatic diseases.
- Italian patients with rheumatic disease have a number of unmet health care needs.
- Biologic therapy improves outcomes and work productivity in patients with rheumatic diseases.

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