

Quality of life in patients with plaque psoriasis treated with biologic therapies

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Summary

Introduction. Numerous published studies have shown impaired health-related quality of life (HRQoL) in patients with psoriasis.

Objective. To evaluate the impact of biologic treatments on HRQoL in clinical practice.

Methods. A prospective observational study was conducted at 12 Psocare Centres in Italy and in-

cluded patients with chronic plaque psoriasis switching to biologic therapy from conventional systemic treatments, or resuming biologic therapy after a suspension of at least 1 year. HRQoL was assessed at enrolment and after 6 months of treatment with biologics.

Results. A total of 185 patients were enrolled, of which 178 were included in the analysis. At enrolment, moderate or severe anxiety and depression were reported by 46.6% and 34.8% of patients, respectively. Psychological problems were unrelated to objective assessments of disease severity. Significant proportions of patients reported sexual problems, embarrassment about their condition and appearance, clothing choices being affected, and concern over possible future effects of the disease. After 6 months of treatment with biologics the proportions of patients reporting these disease-related problems reduced.

Conclusion. This study demonstrated that biologic treatments improve HRQoL in patients with plaque psoriasis. It also highlights the importance of HRQoL as a key measure of the efficacy of treatments for this condition.

KEY WORDS: quality of life; psoriasis; biologic therapy; emotive condition; functional condition.

Introduction

The quality of life dimension is considered fundamental when measuring the outcomes of healthcare technologies. Health-related quality of life (HRQoL) provides a number of advantages over conventional measures of efficacy that are typically based on clinical parameters or mortality rates. Assessment of HRQoL makes it possible, for example, to compare treatments for various acute and chronic conditions. It provides a decidedly holistic measurement of the benefits of different treatments and, at the same time, involves information on measures such as emotional problems and pain that, until just a few years ago, were classified in pharmacoeconomics studies as "intangible costs".

HRQoL can be defined as the level of satisfaction or wellbeing an individual attributes to his/her life. It consequently has a multi-dimensional nature, on account of the complexity of the factors affecting an individual's perception of his/her emotive and functional condition. Quality of life depends, above all, on a set of responses that are dependent on the sensitivity of each individual, and that therefore vary from one patient to another, even

when they have the same medical condition. These include psychological emotive reactions such as the patient's concerns about the disease, anxiety, and depression. It should therefore come as no surprise that quality of life does not coincide with the objective state of health or severity of disease symptoms or with the results of diagnostic procedures.

Psoriasis is a medical condition that does not usually affect survival, but tends to have a profound negative effect on quality of life (1, 2). Psoriasis is an immune-mediated chronic, recurrent disease affecting the skin and joints (1). The most common form, plaque psoriasis, accounts for approximately 80% of psoriasis cases, and is characterised by localised red plaques covered with silvery-white scales, which are often located on the knees, elbows, and scalp (2).

Many studies have observed a significant worsening in the mental and physical wellbeing of patients with psoriasis, including greater difficulty in leading a normal social life (1-3). Although it is not life-threatening and not usually serious, psoriasis is subject to remission with recurrences occurring as long as several years apart. In particular, due to the physical appearance of the lesions, which are often visible to other people, psychological conditions that have a negative influence on social life can develop in patients with psoriasis. A number of studies have shown how the location of the lesions has a decisive influence on the negative psychological effects: more visible lesions lead to stigmatisation, which causes individuals with the disease to isolate themselves and, in some cases, to experience discrimination (4). It is therefore a disease that has a strong influence on the way patients see themselves and others.

One in four patients with psoriasis experiences psychological stress and one in five has psychiatric comorbidities (5, 6). The mental problems associated with psoriasis are numerous and range from poor self-esteem to sexual dysfunctions, and also include psychological symptoms such as depression, suicidal ideation and anxiety (7). The prevalence of depression amongst psoriasis patients varies from 10% to 58% (8, 9). There is also a higher than average incidence of drinking and smoking amongst psoriasis patients (10, 11).

Despite these findings, studies of new treatments have tended to focus on objective symptomatic improvement as the primary measure of efficacy.

The objective of this study was to determine the effects of treatment on quality of life in patients with plaque psoriasis in a cohort of patients in a prospective observational study who switched from conventional systemic treatments to biologic treatment.

Methods

A prospective observational study was conducted to evaluate the HRQoL and living conditions of patients with plaque psoriasis receiving treatment with biologics, as well as utilisation of medical and other resources.

This study was conducted at 12 Psocare Centres in different parts of Italy and enrolled all patients switching to biologic therapy between 11 May 2009 and 31 December 2009 and all those who, during the same period, resumed biologic treatment after at least one year's suspension. The Psocare project was launched as part of a programme promoted by the Italian Medicines Agency (AIFA) and organised in conjunction with dermatology societies and patient associations, under the technical coordination of the GISED research centre. The aim of the project was to evaluate the long-term efficacy and safety of the treatments available, based on comparisons between different care strategies, with a view to obtain a realistic estimate of their benefits and risks. The indications for which biologics are approved in Europe envisage their utilization in cases of moderate to severe plaque psoriasis in patients refractory to, with contraindications for, or intolerant to conventional systemic treatments such as retinoids, cyclosporin A (CsA), methotrexate (MTX) or PUVA. The Psocare project specifies that patients eligible for biologic therapy must have received previous treatment with two or more systemic treatments (acitretin, PUVA, CsA, MTX) which have been either ineffective or associated with significant adverse effects.

Before being offered the chance to switch to treatment with a biologic agent, patients were asked to complete the Euro Qol questionnaire (EQ-5D) by the algorithm derived from a large national survey of the UK population in the early 1990s (12) in order to assess their HRQoL, a series of adjoined questions to measure their utilisation of health resources in the 6 months prior to enrolment and subjective clinical parameters (at the enrolment), including visual analogue scale (VAS) assessments of pain and itching. The patient's physician was asked to fill in another questionnaire containing a number of objective clinical parameters, such as the Psoriasis Area and Severity Index (PASI) score. Enrolled patients were monitored for six months. At the end of the follow-up phase, HRQoL and objective and subjective clinical parameters were measured again.

The series of questions administered to patients at enrolment and at the end of the follow-up period also evaluated other specific aspects concerning the problems caused by their psoriasis, for example their embarrassment regarding their condition and their appearance, the way it affects how they dress, anxiety, depression and isolation at the moment of the interview. Patient's concerns relating the future development of the disease were also evaluated.

The proportion of patients who suffer "Quite a lot" or "A lot" from the issues raised was therefore analysed. The questionnaires were administered using the Computer-Assisted Personal Interviewing (CAPI) method. Those completed by patients included general details and socioeconomic data; retrospective information on the health care resources used in connection with their psoriasis (medication, visits, diagnostics, day hospital and/or outpatient services); direct and indirect costs and the EQ-5D questionnaire. Those completed

by doctors involved the main elements of clinical evaluation (PASI, pain VAS and itching VAS) and information on medication.

Results

The study enrolled a total of 185 patients at the 12 participating centres, with a minimum of seven and a maximum of 43 patients enrolled per centre. Although all enrolled patients completed the follow-up period assuming the biological drug for the entire period of observation, the analysis included 178 patients as one centre withdrew before the project was completed.

At enrolment, i.e. the switch to treatment with a biologic agent, 59.6% of patients were prescribed etanercept, 32.0% adalimumab and 8.4% of patients received infliximab. Patients were aged between 18 and 79 years (mean age of 47.7 years) at enrolment. The average age at diagnosis was 30.6 years, with a minimum age of 1 year and a maximum of 70 years. Although the literature suggests that the prevalence of psoriasis is similar for both sexes (13), in this study the proportion of males was greater (64.6% of patients).

Quality of life prior to switching to biologics

A significant proportion of patients had psychological difficulties and psychological comorbidities (Tab. 1): 46.6% of patients had moderate or severe anxiety and 34.8% had depression, and more than 27.2% of patients reported feeling lonely and isolated. Women appeared to be more prone to these problems, with 63.6% of female patients experiencing anxiety (vs 38.0% of men), 49.1% feeling depressed (vs 27.2% of men) and 36.4% feeling lonely (vs 22.4% of men).

These difficulties were more common in patients who had been widowed and those aged between 40 and 60 years. The prevalence of psychological problems was also confirmed in the anxiety and depression section of the EQ-5D questionnaire: 15.2% of patients claimed they often felt anxious or depressed and 52.2% claimed that they felt anxious or depressed at times. The incidence and severity of psychological problems was not related to the severity of the psoriasis.

Patients also reported impaired personal and sex life: 24.3% of respondents claimed that they had low sexual desire and 23.7% experienced sexual frustration. The problem was more common in women than men (Tab. 2).

The majority of patients reported "quite a lot" or "a lot" of embarrassment about their condition (55%) and embarrassment about their appearance (57.1%), and that their condition affected the way they dress (52.3%) "quite a lot" or "a lot" of the time (Tab. 3). Women were affected to a greater degree than men with respect to embarrassment regarding their condition and appearance and the effects psoriasis has on the way they dress ("quite a lot" or "a lot" reported by 67.3%, 73.2% and 68.5%, respectively, for women vs 48.6%, 48.6% and 43.4%, respectively, for men). Younger subjects (aged 18-49 years) were also more susceptible.

Patients' responses to the "usual activities" section of the EQ-5D questionnaire also indicated that psoriasis significantly impacted on quality of life, with 39.9% of those enrolled reporting that they had difficulties performing their usual activities and 3.4% that they were unable to perform them.

Patients also expressed concern with regard to the disease's future progression (Tab. 4). They were par-

Table 1 - Percentages of patients with disease-related psychological problems.

	Loneliness/ isolation			Anxiety			Depression		
	A little	Quite a lot	A lot	A little	Quite a lot	A lot	A little	Quite a lot	A lot
Total	38.6	22.8	4.4	32.5	33.7	12.9	31.7	24.7	10.1
Sex									
Males	36.9	18.5	3.9	35.2	29.6	8.3	35.9	20.4	6.8
Females	41.8	30.9	5.5	27.3	41.8	21.8	23.6	32.7	16.4
Age									
18-29	43.8	25.0	6.3	12.5	31.3	18.8	18.8	18.8	12.5
30-39	47.4	18.4	0.0	42.1	31.6	2.6	40.5	21.6	0.0
40-49	34.6	23.1	7.7	26.7	40.0	20.0	25.0	32.1	14.3
50-59	30.0	30.0	5.0	20.0	42.5	15.0	26.3	34.2	15.8
60-69	40.0	20.0	5.7	45.7	25.7	14.3	38.2	14.7	11.8
70+	33.3	0.0	0.0	75.0	0.0	0.0	40.0	20.0	0.0
Disease severity									
Mild	41.7	18.8	8.3	30.6	32.7	16.3	29.2	22.9	16.7
Moderate	15.8	31.6	5.3	40.0	35.0	10.0	31.6	26.3	10.5
Severe	41.8	23.1	2.2	31.9	34.0	11.7	33.0	25.3	6.6

Table 2 - Percentages of patients reporting impaired personal and sex life.

	Low sexual desire			Sexual frustration		
	A little	Quite a lot	A lot	A little	Quite a lot	A lot
Total	26.4	16.4	7.9	20.0	17.0	6.7
Sex						
Males	25.3	15.8	6.3	23.1	14.3	6.6
Females	28.9	17.8	11.1	13.6	22.7	6.8
Age (years)						
18-29	30.8	0.0	15.4	15.4	7.7	7.7
30-39	38.2	8.8	2.9	38.2	5.9	5.9
40-49	22.2	22.2	7.4	12.0	24.0	8.0
50-59	14.7	20.6	11.8	11.8	29.4	8.8
60-69	31.0	20.7	6.9	18.5	14.8	3.7
70+	0.0	33.3	0.0	0.0	0.0	0.0
Disease severity						
Milds	68.4	1.8	1.8	20.0	14.3	11.4
Moderate	60.9	4.4	0.0	21.1	21.1	0.0
Severe	53.9	2.6	4.4	19.8	17.3	6.2

Table 3 - Percentages of patients reporting embarrassment and effect on clothing choices.

	Embarrassment about condition			Embarrassment about appearance			Effect on clothing choices		
	A little	Quite a lot	A lot	A little	Quite a lot	A lot	A little	Quite a lot	A lot
Total	27.2	34.6	20.4	31.9	40.5	16.6	22.9	32.0	20.3
Sex									
Males	28.0	33.6	15.0	36.5	37.4	11.2	24.2	34.3	9.1
Females	25.5	36.4	30.9	23.2	46.4	26.8	20.4	27.8	40.7
Age (years)									
18-29	0.0	37.5	43.8	18.8	43.8	31.3	25.0	18.8	43.8
30-39	34.2	39.5	13.2	31.6	47.4	13.2	28.6	31.4	14.23
40-49	17.2	34.5	34.5	17.2	48.3	24.1	25.0	39.3	21.4
50-59	32.5	22.5	22.5	36.6	31.7	17.1	13.2	36.8	23.7
60-69	31.4	42.9	5.7	45.7	37.1	8.6	25.0	31.3	12.5
70+	50.0	25.0	0.0	25.0	25.0	0.0	25.0	0.0	0.0
Disease severity									
Mild	28.6	32.7	20.4	34.7	34.7	18.4	25.0	18.2	20.5
Moderate	31.6	10.5	21.1	42.1	31.6	10.5	26.3	31.6	15.8
Severe	25.5	40.4	20.2	28.4	45.3	16.8	21.1	38.9	21.1

ticularly worried about future bodily changes (22.8%) and an increase in the visibility of the symptoms (37.3%). Almost half of the women interviewed said they were "very" concerned about these aspects. Interestingly, it is the patients with mild psoriasis that are most concerned about the future.

Pain was another factor for which patients expressed concern over future disease progression, with approximately two thirds reporting that they were either "very worried" or "quite worried" about future pain

(32.7% and 34.6%, respectively). Once again, women and patients with mild psoriasis were those most concerned.

Physical impairment and a worsening in mental health were also aspects of significant concern for patients. More than half had "quite a lot" or "a lot" of concern for the future with respect to physical impairment and deterioration of mental health (66.4% and 52.2% of respondents, respectively).

This finding therefore confirms that Italian patients

Table 4 - Percentages of patients reporting concerns for the future.

	Future bodily changes			Increase in the visibility of symptoms			Physical impairment		
	A little	Quite a lot	A lot	A little	Quite a lot	A lot	A little	Quite a lot	A lot
Total	21.6	42.0	22.8	18.1	42.2	37.3	20.1	32.9	33.5
Sex									
Males	22.1	37.5	23.1	21.0	43.8	31.4	21.9	37.1	25.7
Females	20.7	50.0	22.4	13.1	39.3	47.5	17.0	25.4	47.5
Age (years)									
18-29	18.8	68.8	12.5	12.5	43.8	43.8	6.3	50.0	37.5
30-39	29.0	44.7	10.5	26.3	44.7	23.7	31.6	34.2	7.9
40-49	24.1	13.8	48.3	3.3	33.3	60.0	17.2	17.2	51.7
50-59	11.9	47.6	23.8	18.6	44.2	34.9	14.3	31.0	42.9
60-69	21.2	45.5	21.2	20.0	42.9	37.1	20.6	41.2	35.3
70+	50.0	25.0	0.0	50.0	50.0	0.0	40.0	20.0	20.0
Disease severity									
Mild	17.0	29.8	40.4	20.4	32.7	44.9	18.4	34.7	44.9
Moderate	13.6	72.7	4.6	18.2	72.7	9.1	22.7	40.9	22.7
Severe	25.8	40.9	18.3	16.8	40.0	40.0	20.4	30.1	30.1
Physical pain									
	A little	Quite a lot	A lot	Deterioration in mental health					
				A little	Quite a lot	A lot			
Total	21.0	34.6	32.7	23.6	28.6	23.6			
Sex									
Males	24.7	34.3	26.7	23.1	25.0	23.1			
Females	14.0	35.1	43.9	24.6	35.1	24.6			
Age (years)									
18-29	18.8	43.8	25.0	18.8	31.3	12.5			
30-39	34.2	34.2	13.2	35.1	24.3	8.1			
40-49	17.2	10.3	58.6	17.2	27.6	34.5			
50-59	17.95	43.6	30.8	14.6	29.3	36.6			
60-69	14.71	38.2	41.2	27.3	33.3	21.2			
70+	16.67	50.0	16.7	40.0	20.0	20.0			
Disease severity									
Mild	20.8	29.2	45.8	25.0	22.9	25.0			
Moderate	18.2	45.5	22.7	27.4	31.8	9.1			
Severe	21.7	34.8	28.3	21.9	30.8	26.4			

with access to centres specialised in the treatment of psoriasis also experience significant problems and a deterioration in their quality of life. This result can be summarised in an HQoL of 0.6.

Quality of life after switching to biologic treatments

Switching from conventional systemic treatments to biologics was associated with improvements in disease-related problems (Tab. 5). At 6 months' follow-up the proportions of patients with "a lot" of anxiety, depression and feelings of loneliness/isolation decreased by 61.9%, 68.7% and 28.6%, respectively, compared with at enrolment. There were also reduc-

tions in the proportions of patients experiencing low sexual desire (-72.7%) and sexual frustration (-88.9%) compared with at enrolment. Increases were seen in the proportions of patients who were not embarrassed about their condition (+266.7%) and their appearance (+127.6%), and who said that psoriasis did not affect the way they dress (+100.0%). The number of patients who had difficulties performing or were unable to perform their usual activities decreased by 65.3% and 80.6%, respectively, at 6 months' follow-up. Treatment with biologics was also associated with increases in the numbers of patients who had no or few concerns about future bodily changes (+27.3% and +

Table 5 - Change in disease-related problems reported by patients. Values are expressed as percentage variation between enrolment and follow-up at six months.

Degree of concern	Not at all	A little	Quite a lot	A lot
Loneliness/ isolation	38.8	-14.7	-25.0	-28.6
Embarrassment about condition	266.7	20.4	-41.0	-84.8
Embarrassment about appearance	127.6	38.6	-51.7	-84.8
Anxiety	47.0	1.8	-20.0	-61.9
Depression	24.5	-6.0	-10.2	-68.7
Low sexual desire	15.9	-37.8	-39.1	-72.7
Sexual frustration	6.5	-7.4	-39.1	-88.9
Effect on clothing choices	100.0	37.1	-65.3	-80.6

Table 6 - Patients' concerns about future disease-related problems. Values are expressed as percentage variation between enrolment and follow-up at six months.

Degree of concern	Not at all	A little	Quite a lot	A lot
Future bodily changes	27.3	57.1	-23.5	-46.0
Increase in the visibility of symptoms	450.0	70.0	-17.1	-61.3
Physical impairment	22.7	66.7	-25.9	-41.8
Physical pain	73.7	20.6	-8.9	-43.4
Deterioration in mental health	51.3	10.5	-21.7	-60.5
Reappearance of symptoms	25.0	82.6	-3.2	-36.1

57.1%, respectively), an increase in the visibility of symptoms (+450.0% and +70.0%, respectively), or the reappearance of symptoms (+25.0% and +82.6%, respectively) at 6 months (Tab. 6).

At 6 months' follow-up, the fear of physical pain for the future also decreased, with changes of +73.7% and +20.6% in the proportions of patients who were not concerned or only slightly concerned about future pain, respectively.

Compliance improved after switching to biologic treatment, with 12.4% of patients reporting that they had skipped treatment at 6 months, compared with 34.3% at enrolment. The proportion of patients who forget to take their medication on rare occasions decreased from 24.2% to 10.1%, who sometimes forget their medication from 9.6% to 2.2% and who often forget from 0.6% to 0%.

At enrolment, HQoL was <0.25 (very low quality of life) in 21.4% of patients, 0.25-0.50 (low-to-medium) in 4.5%, 0.50-0.75 in 43.8%, and 0.75-1 (high) in 30.3%. The proportion of patients with very low quality of life was higher among males than females (24.4% vs 15.9% of patients). After 6 months of biologic treatment, the proportions of patients with an HQoL of <0.25, 0.25-0.5 and 0.5-0.75 decreased by 76.3%, 50.0% and 44.9%, respectively compared with at enrolment; accordingly, there was a 125.9% increase in the proportion of patients with a score of over 0.75, indicating high quality of life.

After six months' treatment with biologics, there was an overall improvement in the quality of life. Patients had a mean score at enrolment of 0.6, which increased to 0.8 when the questionnaire was adminis-

tered at the end of follow-up six months later, resulting in a benefit of 0.2 QALY gained.

Discussion

Our study confirmed both the psychological difficulties and the presence of psychological co-morbidities in patients with psoriasis seen in earlier studies (5, 6, 8, 9), in patients with plaque psoriasis despite the use of conventional systemic treatments. Comparison of quality of life assessments at enrolment and after 6 months' treatment with biologics showed improvements in psychological problems, sexual function, embarrassment, and concern for the future.

The disability experienced by patients with psoriasis can be compared to that of people with heart problems, diabetes, cancer or depression (2, 13). Indeed, the pre-switching EQ-5D index in the current study is similar to values recorded for patients with conditions such as multiple sclerosis and angina pectoris (14). One study in 425 American patients with psoriasis, two thirds of whom had severe psoriasis, analysing a number of aspects connected to the ability to perform activities of daily living and quality of life showed that 41% experienced great frustration and anger, 35% felt vulnerable and 35% felt embarrassed and ashamed (15). Almost half of the patients claimed that they dress to hide their psoriasis.

Another study, conducted in seven European countries (Belgium, Czech Republic, Finland, France, Germany, Italy and Holland), assessed the impact of psoriasis on activities of daily living using the psoriasis

disability index (PDI) (16). The study showed that the impact of psoriasis on the quality of life is proportionate to the severity of symptoms; for example, activities of daily living are affected in 48% of patients overall, and in a greater proportion of patients with moderate to severe *versus* mild psoriasis (52% *vs* 25%). The condition also led to psychological problems: 27% of patients had sexual problems; 21% had psoriasis-related difficulties in personal relationships and 26% of those interviewed experienced difficulties in their social lives. This study confirms that psoriasis has a negative effect on an individual's personal and sex life, causes anxiety and unfounded shame, and consequently influences social choices in terms of clothing, going out and the way the body is exposed. Overall, we can affirm that the feeling of refusal and sensitivity to the opinions of others are some of the psychological factors that characterise the more vulnerable patients with psoriasis. The knowledge that psoriasis cannot be cured often contributes to depression and stress. This study also demonstrated that psoriasis has a greater psychological effect on women. The main limitation of this study is the short observation period, which did not allow the persistence of the observed benefits to be assessed.

Treatments for psoriasis should be evaluated not only for clinical efficacy but also in relation to their social impact, i.e. benefits in terms of quality of life. The most important characteristics of a treatment for psoriasis would appear to be the ability to keep the condition under control in the long-term and the reduction in pain and skin symptoms (especially those with a high social impact that affect normal social life). These are elements that psychologically reassure the patient, and also lead to a reduction in the problems associated with frequent use of health services and, particularly, hospitalisation.

Before the advent of biologic treatments, four out of ten patients with psoriasis reported frustration at the poor efficacy of the available therapies (a figure that rises to nine out of ten for young patients), and almost one in three patients demanded more aggressive treatments (17). The introduction of biologics for the treatment of psoriasis has provided an efficacious option that reduces symptoms, improves mental and physical function and improves quality of life.

In general, treatment with biologics is associated with a significant increase in the proportions of patients with no or few concerns about a possible increase in the visibility of symptoms, reappearance of symptoms, pain, deterioration in mental health and future bodily changes and physical impairment.

Consistent with other published studies on this subject, the current study confirms that Italian patients attending centres specialised in the treatment of psoriasis experience considerable discomfort and deterioration in quality of life and that biologic therapy considerably reduces disease-related problems, thereby having a significant impact on HRQoL. More specifically, it shows that the psychological aspects of the disease strongly influence patients' quality of life. In patients eligible for treatment with biologics, this is partly unrelated to the severity of the disease, where

as it is to a great extent affected by anxiety regarding the future prospects for their condition. After switching to biologic therapy, these anxieties were significantly reduced, which led to a significant increase in patient's optimism regarding their future.

Conclusion

Due to the significant negative effect of psoriasis on both physical and mental aspects of quality of life, treatments for this condition should be evaluated not only in terms of their clinical efficacy, but also their impact on patient's living conditions, including psychological well-being. Biologic agents have been shown to improve disease symptoms and, as shown in the current study, quality of life in patients with psoriasis. The introduction of biologic agents therefore represents an important therapeutic option for the treatment of psoriasis.

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