

Health-related quality of life in psoriasis: an analysis of Psocare project patients

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Aim. Psoriasis is a common, chronic, immune-mediated skin disorder that may be complicated by psoriatic arthritis in up to one-third of patients. Psoriasis treatments are increasingly effective, yet more expensive, thus requiring rational decision-making on interventional priorities. The ability to perform cost-utility analyses is hindered by the lack of algorithms that allow the inference of utility measures, like QALY, from specific dermatological health-related quality-of-life (HR-QoL) measures (e.g. Dermatology Life Quality Index [DLQI]). This study aimed to assess whether psoriasis-related HR-QoL data (DLQI) could be used to obtain utility measures for use in economic analyses.

Methods. Psoriasis patients attending 11 Italian Psocare project treatment centers over a 19-day period were enrolled and completed a questionnaire, including several HR-QoL scales and sociodemographic/clinical data, and underwent a clinical examination. Data were subjected to a Multiple Correspondence Analysis and multiple regression analysis to determine the contribution of single items to the HR-QoL.

Results. DLQI and Psychological General Well-Being Index (PGWBI) scores were most closely correlated with the EuroQol health status index. Age and gender were considered confounding factors, while pain and arthritis contributed significantly to HR-QoL deterioration. For disease severity, the need for hospitalization and the number of examinations, but not the Psoriasis Area Severity Index (PASI), contributed to HR-QoL deterioration.

Conflicts of interest.—The authors declare that they have no competing interests directly related to this manuscript

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Conclusion. Recent historical clinical and HR-QoL data from psoriasis patients can reproducibly define a health status index, such as the EuroQol SD-5Q, that could be used reliably to estimate QALYs for use in cost-utility analyses to compare the cost-benefit profiles of competing therapies.

KEY WORDS: Quality of life - Psoriasis - Costs and cost analysis.

Psoriasis is a chronic, immune-mediated disease that most commonly manifests as red/silvery-white scaly plaques on the skin, although up to 30% of patients may also develop inflammatory arthritis

as a complication.¹ Psoriasis is a common skin disorder that affects approximately 2.7% of the adult population in Italy,² of whom about 10% have severe disease resulting in occasional hospitalization.¹ Although patients may experience extended periods of remission, long-term therapy is often required for moderate-to-severe psoriasis.³

While newer systemic therapies for psoriasis with the use of biological agents¹ are becoming increasingly effective, they are also more expensive than traditional treatments. Widespread access to innovative therapies in clinical practice is hindered by limited resources, requiring rational decision-making on interventional priorities. The different impact of therapies, some of which may succeed in lengthening life, while others improve patients' health-related quality of life (HR-QoL), has caused the international community to recommend evaluations based on the cost-utility approach. However, this requires specific measures of HR-QoL suitable for directly calculating standardized utility measures such as QALYs.

Psoriasis does not significantly modify patients' life expectancy, but significantly reduces their QoL.⁴⁻⁷ The disease is subject to remittances and relapses, even after periods of years, and considerably affects patients' lives. In particular, the aesthetic aspects of psoriatic lesions are likely to result in psychological problems that make it difficult for patients to lead a normal social life.^{8,9} Greater alcohol intake or tobacco smoking among patients suffering from psoriasis has been reported.¹⁰⁻¹²

The Psocare project in Italy, promoted by the Italian Drug Agency (AIFA) to evaluate the effectiveness and long-term safety of available psoriasis treatments,¹³ has collected a wealth of information potentially useful for defining a model for the use of retrospective data in future cost-utility analyses.

The aim of this study was to use information derived by the Psocare project to assess the impact of psoriasis determinants on patients' HR-QoL and to determine whether scores from HR-QoL scales developed for dermatological disorders could be used to obtain a utility measure for use in economic analyses.

Materials and methods

Patients with psoriasis, irrespective of severity, who presented between May 5 and May 23 2008 at

any one of 11 centers in northern, central and southern Italy participating in the Psocare project, were enrolled in the study.

The Psocare project is a psoriasis research programme implemented by the Italian Drug Agency in cooperation with scientific dermatological societies and patient associations, and is coordinated by the GISED (Italian Group for Epidemiologic Research in Dermatology) Study Center. The Psocare project is designed to assess the relative effectiveness and long-term safety of available treatments in terms of risk-benefit profiles.

The Local Ethical Committee of each center approved the study protocol and all patients signed an informed consent before inclusion. The study was conducted in accordance with the Helsinki Declaration.

Enrolled patients completed a questionnaire composed of five sections containing the following information: 1) socio-demographic data (age, gender, marital status, educational qualifications, occupational status), medical history in the past year, hospitalization details, work days lost or with reduced productive capacity, days in which recreational activity was missed, and lifestyle (tobacco smoking, alcohol intake); 2) the 10-item DLQI questionnaire (maximum possible score = 30, with higher scores representing greater impairment of QoL) covering the previous 7-day period, which evaluates QoL in patients affected by a dermatological pathology;¹⁴ 3) the 22-item PGWBI questionnaire (maximum possible score of 110 representing best achievable "well being") which assesses the impact of disease on psychological well-being (anxiety, depression, positiveness and wellbeing, self-control, general state of health and vitality) over the previous 4 weeks; 4) the EuroQol EQ-5D questionnaire which generates a single index value for health status ranging from 0 to 1, with 1 representing a perfect state of health; and 5) information, completed by the physician, concerning the type of psoriasis, the location of the lesions, any co-morbidity associated with the disease, prescribed pharmacological therapies and severity of the disease, the latter codified through the use of the PASI. Sections 1-4 were completed by the patient prior to examination by the physician in order to prevent the patient's psychological evaluation from being influenced by the meeting with the physician.

A two-step approach was adopted in order to detect the contribution of the various factors to health-

related QoL and, therefore, to isolate those related to the disease.

A multiple regression analysis was used to determine the contribution towards the HR-QoL (as determined by the EuroQol) of QoL aspects related to the disease pathology (DLQI), the psychological dimension (PGWBI), the clinical state, and the discomfort arising from the recourse to the healthcare services. Aspects linked to socio-economic and demographic factors were taken into account as they can be considered as confounding factors.

Since there were a number of socio-economic variables that are qualitative (such as marital status, the level of education and occupational status), the MCA was used to explore the latent dimensions of the phenomena. The recourse to this technique is useful in the presence of both qualitative (or quantitative ordinal) and quantitative variables; in fact, starting from the statistical association between qualitative variables, the MCA allowed a summary of the information contained in the original variables, producing new quantitative-type variables (factors). Due to the fact that, in our model, one factor alone actually explained more than 70% of the variance, it has been used as an indicator for summarizing the aforementioned categorical variables in the subsequent statistical analysis.

Therefore, the regression analysis model assumed the following equation for the EuroQol score: $\text{EuroQol} = f(Q; C; P; SDE)$, where:

— Q (elements of QoL): DLQI score, PGWBI score, lost days (work and/or spare time), tobacco smoking and alcohol intake;

— C (clinical factors): type of psoriasis, symptomatology, location, co-morbidity, pharmacological therapy, PASI score;

— P (discomfort in being subjected to clinical treatments): number of hospitalizations, specialist examinations, examinations by general practitioner, frequency of laboratory tests, number of psychotherapies;

— SDE (socio-demographic and economic variables): first MCA factor (occupational status, level of education, marital status), gender, age.

Following a stepwise procedure used using SAS software, the above-mentioned variables were progressively added to the regression model: at each step a single variable was added, following the criteria of choosing the variable explaining the greatest share of model variance, under the constraint

TABLE I.—Patient (N.=372) demographic details.

Men/women (%)	69.2/30.8
Age (years; range)	49.1 (19–86)
Education (%)	
University degree (or higher)	10.1
High school diploma	30.8
Vocational diploma or qualifications	13.0
Junior high school leaving certificate	30.8
Elementary school leaving certificate	14.8
No educational qualifications	0.6
Marital status (%)	
Single	19.6
Married	71.7
Separated/divorced/widowed	8.7
Occupational status (%)	
Employed	62.7
Pensioner	18.8
Housewife	10.0
Unemployed	4.3
Student	2.0
Unfit for work/seeking first job	2.3

Values are mean unless otherwise noted; sum of percentage may exceed 100% due to rounding

that each variable should be significant at least at the 85% level. The stepwise procedure ended when no more variables passed the constraint.

Results

Enrolment

Three hundred seventy-two patients were enrolled in the study; their demographic details are shown in Table I, Figures 1, 2. The mean patient age was 49.1 years and 69.2% of patients were male. Patient gender, educational status, marital status and occupational status were not evenly distributed between all of the 11 centers. Most patients (72.3%) had mild disease (Table II) and nearly 57% of patients had PASI values between 0 and 5 (Figure 1), indicating that many patients already undergoing treatment may have visited the control center during a period of disease remission.

Enrolled patients visited their family doctor an average of 4.2 times per year and over 50% of patients reported, on average, a general hospitalization

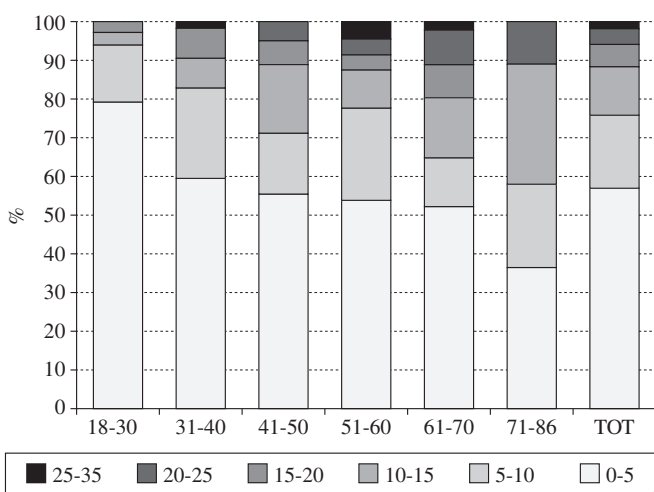


Figure 1.—PASI values by age.

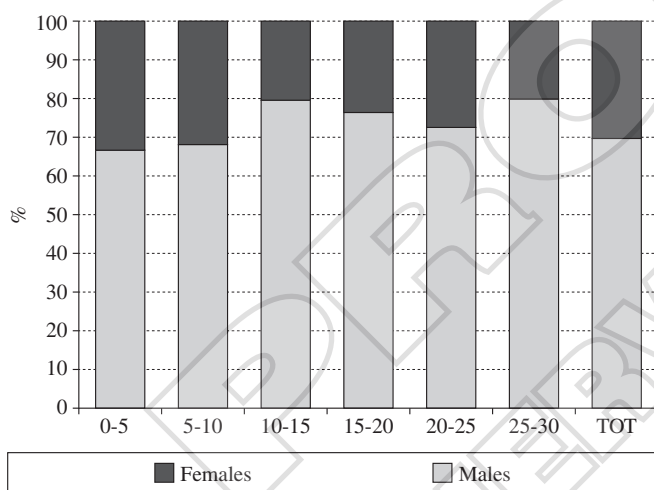


Figure 2.—PASI values by gender.

per year (Table II). Patients experienced an average of 4.6 examinations per year by a dermatologist and one additional examination per year by a specialist other than a dermatologist (Table II). Although there was considerable variability between patients and treatment centers, each patient underwent an average of 5 ultraviolet B (UVB) irradiations and 1.3 psoralen plus ultraviolet A (PUVA) irradiations per year. Most patients had monthly or quarterly frequency of laboratory tests (Figure 3). Patients lost an average of nearly one day of work per month and reported a reduced working capacity for one other day each

TABLE II.—Patient disease history, status and health resource utilization.

Average age at appearance of initial symptoms (years; range)	30.9 (2-85)
Average age at diagnosis (years; range)	32.8 (3-85)
Average duration of disease (years)	18.6
Mean PASI at enrolment (median)	7.1 (4.9)
Psoriasis severity (%)	
Mild	72.3
Moderate	20.0
Severe	7.7
Annual hospitalizations (average number)	
Dermatological hospitalization	0.49
Dermatological day hospital	1.24
Other hospitalizations	0.14
Annual examinations (average number)	
Family physician	4.24
Dermatologist	4.62
Other specialists	0.99
Psocare Center visits	2.40
Annual specialist services (average number)	
Radiographs (chest and other)	0.73
Scans (ultrasound or CAT)	0.39
UVB treatments	4.77
PUVA treatments	1.27
Laboratory tests (%)	
Monthly or more frequent	28.3
Quarterly/semi-annual	52.3
Annual	18.4

PASI: Psoriasis Area and Severity Index; CAT: computed axial tomography; UVB: ultraviolet B irradiation; PUVA: psoralen plus ultraviolet A irradiation.

month. On average, each patient also gave up recreational activities as a result of their disease on 1.3 days per month.

HR-QoL

Patient scores on the three HR-QoL questionnaires are shown in Table III, Figures 4-6. On the DLQI questionnaire, which is specifically designed for dermatological pathologies, 18% of patients reported scores indicating severe impairment of HR-QoL (>12). Severe impairment was greatest in the 40-50 year age class, in which nearly 30% of patients had scores >12.

For the PGWBI questionnaire, that specifically assesses the impact of psychological stress on QoL,

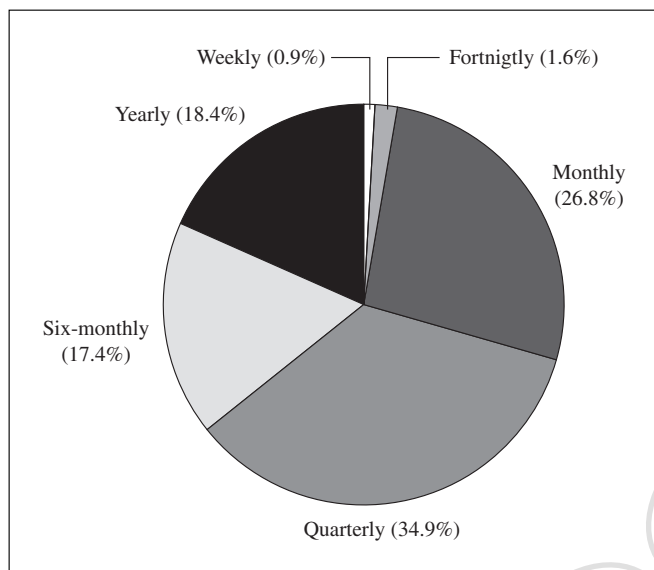


Figure 3.—Frequency of laboratory tests.

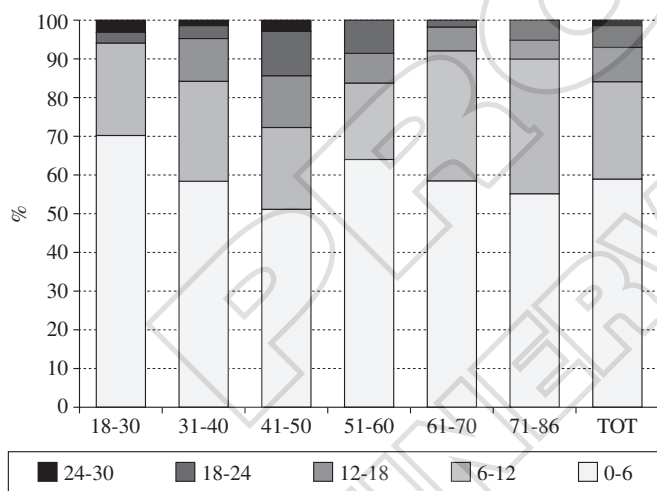


Figure 4.—DLQI values at various ages.

women were impaired more than men. On the generic EuroQol index, there was a general deterioration of QoL with increasing age, with women generally reporting worse QoL than men.

On analysis of the correlations between the three HR-QoL scales (Table IV) and other variables, such as disease severity measured by the PASI scale, it was noted that the DLQI and the PGWBI indexes were most closely correlated with the EuroQol, with

TABLE III.—Patient scores on three HR-QoL questionnaires.

	Average score (±SD)	Median score
DLQI	6.8 (±6.5)	5
PGWBI	72.7 (±18.4)	74
EuroQol	0.74 (±0.27)	0.66

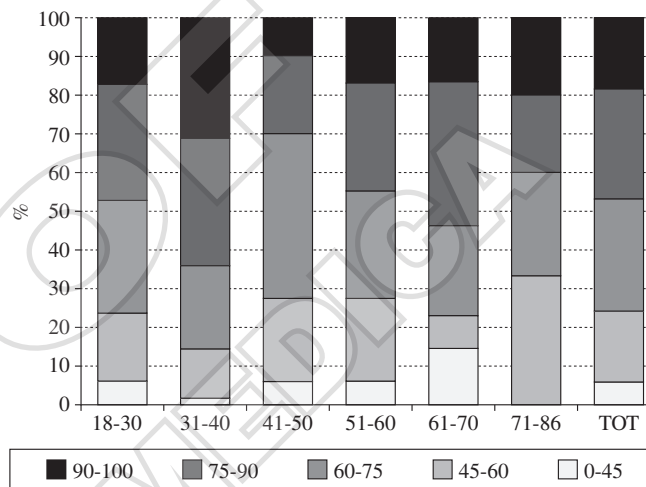


Figure 5.—PGWBI values at various ages.

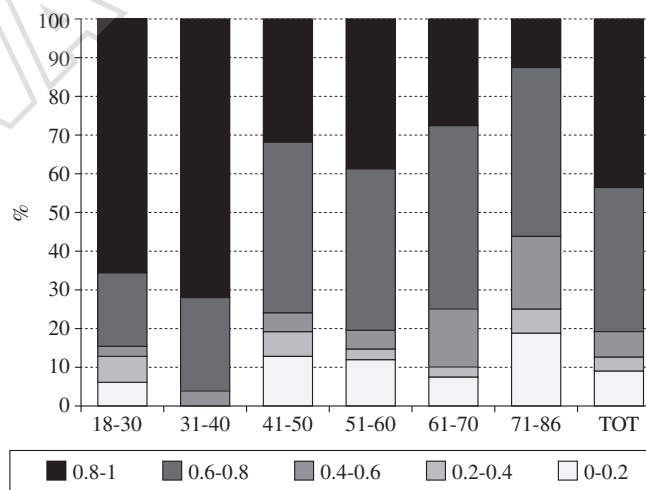


Figure 6.—EUROQoL values at various ages.

the anticipated signs (negative for the former and positive for the latter). Age was negatively correlated with the EuroQol and PGWBI scores and positively correlated with the DLQI, consistently indicating a

TABLE IV.—Correlation indexes among HR-QoL scales, PASI and patient age.

	EURQol	PGWBI	DLQI	PASI	Age
EURQol	1.00	0.54	-0.39	-0.15	-0.09
PGWBI	0.54	1.00	-0.55	-0.24	-0.10
DLQI	-0.39	-0.55	1.00	0.36	0.07
PASI	-0.15	-0.24	0.36	1.00	0.24
Age	-0.09	-0.10	0.07	0.24	1.00

TABLE V.—Summary of model.

	Values
Root mean square error	0.2085
Dependent mean	0.7469
Variation coefficient	27.9159
R2 (Coefficient of determination)	0.4166
Adjusted R-square	0.3871

progressive deterioration in QoL with age, although the correlation was quite weak. The PASI was negatively correlated with the EuroQol, but the correlation was slight and may have resulted from the numerous low PASI scores in patients assessed during a period of disease remission despite having had severe disease pathology.

Multivariate regression analysis model

The results of the stepwise multivariate regression analysis showing the contribution of the listed variables to the decrease in QoL as measured by the EuroQol health status value are summarized in Tables V-VII. The resulting model explains the 41.7% total variability of the EuroQol score dependent variable.

All of the variables maintained by the stepwise procedure have the anticipated sign. Even though the PASI and MCA variables lacked significance, they were maintained in the model owing to the importance that they have for the analysis. Both the DLQI and PGWBI score variables were statistically significant.

The severity of the pathology, as measured by the PASI, did not contribute to the decline in HR-QoL, probably because the PASI was often determined during periods of remission and so failed to measure the true level of severity in these patients. Nonetheless, a few aggravating symptomatology, such as the perception of pain and the presence of arthritis, contributed to the deterioration in HR-QoL.

Of the aspects linked to the severity of the disease, the recourse to clinical services and, in particular, the need for hospitalization and the annual number of examinations adversely affected HR-QoL and seemed to be a marker for its deterioration.

Patient age contributed significantly to the explanation of the deterioration in HR-QoL, as measured by the EuroQol, in addition to the increased severity and symptomatology of psoriasis associated with aging, and could thus be considered a confounding factor.

Gender was linked to the decrease in HR-QoL, with women having greater reductions in HR-QoL than men, on average. It appeared that age and gender were the only socio-economic variables playing a significant role in the reduction in HR-QoL; factors constructed with the MCA (including such items as marital status, level of education and occupational status) did not prove significant.

Discussion

Psoriasis is a genetically determined disease that affects up to 3% of the population worldwide.¹ It is a chronic disease that generally waxes and wanes during a patient's lifetime and has a few spontaneous remissions, especially in the plaque-type, widely spread form. Adequate long-term treatment of psoriasis is required, particularly in moderate-to-severe cases, as this disorder substantially impacts patients' HR-QoL.⁴⁻⁷ Psoriasis is considered to be associated with reductions in HR-QoL comparable to other chronic diseases such as arthritis, hypertension, heart disease, cancer, diabetes and depression.¹⁵ Retinoids, ciclosporin, methotrexate and PUVA therapy have been used for many years as traditional systemic treatments.³ Biological agents, such as tumour necrosis factor (TNF) antagonists, are the latest therapeutic agents to be approved and they usually act

TABLE VI.—ANOVA analysis.

	Degree of freedom	Sum of squares	Mean of squares	Value F	Probability (95%) > F
Model	11	6.7676	0.6152	14.1500	0.0000
Error	218	9.4784	0.0435		
Adjusted total	229	16.2460			

TABLE VII.—Coefficient.

Variables	Degree of freedom	Estimate of parameters	Standard error	Value t	Probability (95%) > t
Intercept	1	0.6418	0.1254	5.1200	0.0000
DLQI score	1	-0.0328	0.0181	-1.8100	0.0706**
PGWBI scores	1	0.0059	0.0010	5.6900	0.0000***
PASI	1	0.0376	0.0339	1.1100	0.2684
Pain	1	-0.1048	0.0427	-2.4400	0.0150**
Arthritis	1	-0.0494	0.0335	-1.4700	0.1416*
Number of hospitalizations	1	-0.0344	0.0132	-2.5900	0.0100***
Number of specialist examinations	1	-0.0094	0.0061	-1.5200	0.1273*
Age	1	-0.0045	0.0010	-4.2900	0.0000***
Gender	1	-0.0526	0.0324	-1.6100	0.1060*
MCA	1	-0.0270	0.0358	-0.7400	0.4530

***99% significant; ** 95% significant; *85% significant.

relatively quickly and effectively, even in the most severe forms of psoriasis and psoriatic arthritis.¹⁶ They are generally prescribed in non-responders to traditional treatments, or if the patient has contraindications to, or a history of adverse effects to one or more, traditional antipsoriasis therapies.¹⁷

Current therapeutic regimens often allow the skin manifestations of the disease to be kept under control, as shown by the low PASI score reported for many patients enrolled in this study, despite having been referred to centers specializing in the treatment of moderate-to-severe psoriasis. However, these innovative therapies incur a considerable cost that has repeatedly caused the Italian Drug Agency to monitor the sector with care.¹⁸⁻²⁰ Therefore, in an arena of scarce resources, special relevance is associated with the ability to compare the cost-benefit profiles of such therapies with those of other therapeutic opportunities appearing on the market. Internationally, cost-utility studies are generally considered the reference analyses for such comparisons, but require the use of a utility measure, such as the QALY.

In psoriasis, such an approach would seem to be particularly advisable considering the chronic pathology of the disease, often characterized by an ear-

ly onset (among the patients enrolled in the current study, the disease developed on average at about 30 years of age) and a relapsing/remitting course over the patients' entire lifespan (on average, the patients enrolled in this study had psoriasis for over 18 years). Thus, the achievable QoL that can be maintained represents a fundamental endpoint for the evaluation of the benefits of psoriasis therapies.

The wealth of information collected by the Psocare project may be beneficial in detailing the therapeutic strategies adopted in Italy and in analyzing their effectiveness/efficiency. However, the ability to conduct cost-utility analyses is hindered by the lack of HR-QoL-related utility measures specific to the dermatological field that can be used to estimate QALYs for patients undergoing treatment.²¹

This study has shown that recent historical data, including HR-QoL information that relies on patients' memory, may be used to construct a model that succeeds in defining a health status index such as that for the EuroQol SD-5Q. The resulting model had a reasonably good predictive performance, since it accounted for over 40% of the variability of the dependent variable.

Analysis of the contribution of the various factors

involved is of particular interest. The psychological aspect was particularly important to HR-QoL, as shown by the contribution of the PGWBI score. This would seem to be consistent with the fact that the perceived QoL was low even for patients whose disease was less severe, and this could be explained by the psychological expectation of a relapse of the disease.

On the other hand, the social stigma and the psychological impact linked to the aesthetic dimension of the disease pathology have been previously reported,^{6,9} confirming the importance of the psychological factor.

The QoL measures that have been developed for use in the dermatological field encompass features closely linked to purely clinical aspects. Repeated statistical analyses have shown that the DLQI score is very effective in capturing clinical-dermatological aspects in psoriasis patients; however, it does not assess symptoms belonging to other domains.

Non-dermatological clinical factors that contributed significantly to the model were arthritis and pain symptoms. While this suggests that the DLQI is deficient in not accounting for these variables, it does provide useful information for the therapeutic management of psoriasis, with respect to avoiding or delaying the onset of arthritis and the need for analgesia.

The ability of therapies to keep the disease under control for prolonged periods of time affects the extent to which patients are adversely affected by the need for visits to healthcare facilities (examinations, hospitalization, etc.) in order to manage their disease. The frequency of recourse to healthcare services quite possibly encompasses the disease severity element.

In the model used in this study, age and gender are considered as confounding factors. Of course, QoL deteriorates with increasing age. With regard to gender, women experienced lower HR-QoL than men, an inequality that might be remedied by more effective therapies.

Psoriasis had an important impact on HR-QoL in this study, with nearly 20% of patients on average reporting reductions greater than 40% in their long-term QoL. The level of reduction reached 45% in patients aged >70 years, notwithstanding the confounding potential of age referred to above. Overall, more than 50% of patients reported a reduction of at least 20% in their HR-QoL.

Conclusions

Recent historical clinical and HR-QoL data from patients with psoriasis can be used to reproducibly define a health status index, such as the EuroQol SD-5Q, that could reliably be used to estimate QALYs for use in cost-utility analyses to compare the cost-benefit profiles of competing therapies.

Riassunto

Obiettivo. La psoriasi è un frequente disturbo cronico, immuno-mediato, che può presentare complicanze (per esempio, artrite psoriasica) in ~30% dei pazienti. I trattamenti della psoriasi sono sempre più efficaci; tuttavia, il loro costo rende necessario un attento decision-making. La possibilità di condurre analisi di costo-utilità è limitata dalla mancanza di algoritmi che valutano l'inferenza delle misure di utilità, come il QALY, da specifiche misure di HR-QoL in ambito dermatologico (per esempio il DLQI). Questo studio valuta se i dati di HR-QoL psoriasi-correlati possano essere utilizzati per ottenere misure utili per l'analisi economica.

Metodi. Pazienti psoriasici valutati, nell'arco di 19 giorni, in 11 centri del programma Psocare hanno compilato un questionario comprendente diverse scale HR-QoL e valutazioni socio-demografiche e cliniche. I dati sono stati analizzati mediante Multiple Correspondence Analysis e regressione multipla per determinare il contributo di ogni singolo elemento alla HR-QoL.

Risultati. Gli scores DLQI e PGWBI sono immediatamente correlati all'EuroQol health status index. Età e sesso sono risultati fattori confondenti, mentre il dolore e l'artrite hanno contribuito significativamente al peggioramento dell'HR-QoL. Per quanto riguarda la gravità della malattia, la necessità di ospedalizzazione e il numero di valutazioni hanno contribuito al peggioramento dell'HR-QoL, a differenza del Psoriasis Area Severity Index (PASI).

Conclusioni. La storia clinica recente e i dati di HR-QoL dei pazienti psoriasici possono essere utilizzati per definire un indice dello stato di salute, come l'EuroQol SD-5Q, che permette di stimare i QALY nel corso di analisi di costo-utilità volte a confrontare i profili di costo/beneficio di diverse terapie.

Parole chiave: Qualità della vita - Psoriasi - Costi e analisi dei costi.

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