

ORIGINAL PAPER**Moderate and Severe Plaque Psoriasis: a Quality of Life and Cost-of-Illness Study from Greece****Alexis Samoutis, MD, MSc, PhD**

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Abstract

Background: Psoriasis worldwide prevalence is estimated between 1% and 3%. In Greece, prevalence is around 2% and affects approximately 200.000 patients. The most common form of the disease is chronic plaque psoriasis that affects about 80% of psoriasis patients of which more than 10% present a moderate or severe form of the disease. Data and information concerning the quality of life of the patients with a moderate and severe condition, and the economic impact of the disease is limited worldwide and particularly in European countries. The primary objective of this study was to evaluate the quality of life of patients with moderate and severe psoriasis, an intangible cost of the illness, as well as to evaluate the economic impact of the illness in Greece from patient and third-party payer (insurance funds) perspectives.

Methods/Design: Two different questionnaires, SF36 and DLQI were used to evaluate patients' quality of life (QoL). Evaluation of the economic impact of the disease was done by identifying the direct health care cost, through a microeconomic evaluation of all the health care costs, and the loss of productivity, using the human capital approach. Our study included consecutive patients from the Venereal and Skin Diseases Hospital "Andreas Syggros" in Athens, during the period January-December 2005. The inclusion criteria were: age > 18 yrs, PASI (Psoriasis Area Severity Index) >12 and BSA (Body Surface Area) >10%. Patients enrolled in the study were re-assessed after a 3-month period, which was set as the observation period.

Results: The sample for the quality of life assessment study included 177 patients. Ninety-seven patients were re-assessed after the three-month period and their data were used to evaluate the economic impact of the illness. The majority of patients in the study were men with a mean age of around 50. According to the results, both moderate and severe psoriasis affect negatively the patients' quality of life in every aspect examined. In particular, it mostly affects their mental and emotional situation. During their first visit, the patients mean score of PASI was 20.17 and BSA was 29.81%. During the patients' 2nd visit, 3-months later, the mean PASI and BSA scores were 8.44 and 14.89% respectively. Specifically, 67 out of the 97 patients (69.1%) achieved a PASI 50, whereas 37 of them (38.1%) achieved a PASI 75. The economic consequences of the illness are extremely high, since the average total cost per patient was estimated to be €12,455.91 per year. In part this is due to the chronic state of the disease, but is mainly due of the induction of biological medicines in the disease management

Conclusion: Moderate and severe plaque psoriasis has a profound impact on the affected Greek patient's QoL and is associated with extremely high costs. Although biological medicines can contribute to improvements of patient's QoL strictest compliance with disease management guidelines as well as introduction of generic biological medicines will significantly mitigate the increasing cost of this chronic disease.

Keywords: psoriasis, quality of life, cost of illness

Background

Health economics is of growing importance in all health-care systems. Precise cost data are needed for decisions in health care and health policy making. Therefore, economic evaluations are necessary in order to make appropriate use of different treatment options (Williams et al 2008). Cost-of-illness studies are a well-recognized tool to evaluate the financial burden of diseases in a country and to identify subgroups for which the costs are particularly high (Ament A and Evers S 1993).

Psoriasis is an autoimmune chronic inflammatory skin disorder that worldwide affects approximately 1–3% of the population (Nevitt & Hutchinson 1996, Plunkett et al 1998, Naldi 2004). In Greece, prevalence is estimated at around 2% and affects about 200.000 people. The most common form of the disease is chronic plaque psoriasis that affects about 80–90% of psoriasis patients of which 20–30% present a moderate or severe form of the disease (Sterry et al 2004). The chronic and aesthetically unpleasant nature of the disease affects negatively the patients' quality of life (Krueger et al 2001).

Psoriasis severity is defined by the extent of body surface involved, the lesion characteristics and the impact of the disease on quality of life (QoL) (Finlay et al 2005). Patients with a body-surface involvement higher than 10%, or a Psoriasis Area Severity Index (PASI) >10, or a Dermatology Life Quality Index (DLQI) >10 are considered appropriate candidates for systemic therapy (Kirby et al 2000, Shikhar et al 2003, Menter A. et al 2008). More than 10% of the patients also have psoriatic arthritis (Veale & FitzGerald, 2002, Parisier et al 2007).

The disease is usually persistent and progressive and patients usually need lifelong care, which also means a lifetime of expenses (Galadari et al 2001). From an economic perspective, many influencing factors must be taken into account, such as the costs related to prescription drugs, over-the-counter (OTC) and self-care products, hospitalizations, productivity loss due to absence from work for sick leave, and time spent by patients in medical consultations, treatments, or diagnostic procedures (Braathen et al 2001, Dehkharghani

et al 2003). Limited information about quality of life and the economic impact of psoriasis in European countries is available, especially after the induction of the biological medicines in the treatment of the illness (Naldi L 2005). Therefore, we conducted a study to evaluate the patient's quality of life, the direct healthcare costs and the loss of productivity related to moderate and severe plaque psoriasis in Greece.

Patients and methods

Design

We collected QoL data using two questionnaires. The SF36 (short form, 36 questions) general health status survey and the Dermatology Life Quality Index (DLQI) questionnaire, a 10-item dermatology specific instrument. We carried out a 3-month observational, prospective cost-of-illness study of moderate and severe plaque psoriasis. Direct healthcare costs and loss of productivity were considered from the patient and third-party payer (insurance funds) point of view. The study design included also two medical examinations, at baseline and after 3 months.

From January 2005 through December 2005, patients with moderate and severe psoriasis attending the Venereal and Skin disease Hospital "Andreas Syggros" in Athens were invited to participate in the study. Consecutive patient enrolments occurred over 1 year in order to minimize seasonal fluctuations.

Inclusion criteria

Patients aged 18 years and above with moderate to severe plaque psoriasis defined as PASI score higher than 12 and a BSA higher than 10% were included in the study. PASI and BSA score are the most accepted and widely used measures to assess disease severity and improvement in clinical trials and practice (Richard G et al 2004). The study was approved by the local ethical committees and the Declaration of Helsinki protocols were followed. Written informed consent was obtained from all participants.

Data collection

Patients were invited to participate in the study at the time of their dermatological examination.

At the dermatological examination (Visit 1), the evaluating physician completed the “dermatologist questionnaire”, containing data on medical history, physical examination, and any concomitant drug both topic, systemic (such as methotrexate, cyclosporine etc) and biological. During the first visit, patients completed the two self-administered questionnaires, DLQI and SF-36. Patients also were given another self-administered questionnaire named “patient questionnaire”, to be completed on the first and second examinations. The “patient questionnaire” registered data on socio-demographic characteristics and loss of productivity. Patients were asked to keep all drug packs (including cream tubes) that would be used in the next quarter, in order to verify real drug consumption (compliance). Patients were evaluated again after 3 months (± 15 days) during their second visit. The following data were collected: results of physical and laboratory examinations (including diagnostic procedures), the number and time of hospitalizations, concomitant drugs, non-conventional treatments, concurrent visits by dermatologists and other medical specialists, and working days lost in the previous quarter.

Quality of life

In order to assess the patients' quality of life, they were asked to fill in the SF-36 and the DLQI questionnaires. The SF-36 is a multi-purpose, short-form health survey with 36 questions (Ware JE and Donald Shebourne C 1992, Ware et al 1993, Ware et al 2000). It yields an 8-scale profile of functional health and well-being scores, as well as psychometrically based physical and mental health summary measures, and a preference-based health utility index. It is a generic measure, as opposed to one that targets a specific age, disease, or treatment group. The DLQI is a dermatology-specific measure which consists of 10 questions related to patient's symptoms and feelings, daily activities, leisure, work or school, personal relationships and treatment over the previous one week. The total DLQI ranges from 0 (no impairment of QoL) to 30 (maximum impairment of QoL) (Finlay AY

and Kahn GK 1994, Lewis V and Finlay AY 2004).

Costing

The direct health sector costs and the patients' loss of productivity of the present study were assessed as follows:

1. Direct costs

Medical costs studied were: a) hospitalization, b) day-hospital admissions, c) specialist medical examinations, d) laboratory tests and diagnostic procedures, e) phototherapy, f) drug therapies. These costs are based upon the fixed prices set by the Ministry of Health (2005) and paid by health insurance funds. Health care services provided by the private sector and other private costs were evaluated based on the actual expenses incurred in by the patients. All pharmacological therapies (topical, systemic and biological) were considered in the questionnaire. To assess the costs of prescribed pharmacological therapies, units of consumed resources were multiplied by the prices reported in the official Greek price list, taking into consideration the dosage and duration of the treatment. Non conventional treatments were also assessed. All costs are expressed in Euros.

2. Loss of productivity

The human capital approach was used to estimate the productivity loss due to plaque psoriasis (Luce et al 1996). Travel costs were not collected. Loss of productivity included the value of lost production due to leaving work earlier than usual in the day and sick leave. Patients' time off work was measured in terms of salary evaluation, with the assumption that income reflects productivity. The monetary value of 1 lost working day for patients was calculated as €27, equal to the wage of an unskilled worker in 2005.

Statistical Analysis

Statistical analysis were performed using SPSS (version 13.0) Firstly, exploratory data analyses were performed in order to provide all the frequencies on all variables of the questionnaire. These descriptive analyses included distribution patterns (ranges, means, medians, skewness), missing values, and outliers on quantitative variables.

The statistical methods included t-test and chi-square test for categorical variables such as employment status, marital status, gender etc.

Results

1. Quality of life study

Population

Table 1 illustrates the main socio-demographic and disease characteristics regarding the quality of life study. The mean age of the 177 patients examined (119 males (67%) and 58 females (33%)) was 49.85 years. The majority (n=99, 55.9%) were employed, while 44.1% (n=78) were unemployed or retired. Also, the majority (n=140, 79%) were married, while 21% (n=37) were single, divorced or widow. The mean age during the first diagnosis was 33.16 years. The mean PASI score was 20.25 and mean BSA score was 29.8%

SF36 and DLQI scores

Tables 2, and 3 show the SF36, and DLQI questionnaires scores. The worst scores on the SF36 questionnaire were recorded on the General Health and Mental Health scales. Figure 1 compares the results of the SF-36 questionnaire in the study population with the mean values of the general population (Pappa E. et al, 2005). All the scores were below the mean, thus confirming the high impact of plaque psoriasis on the QoL of patients. On the DLQI questionnaire, the worst score was with respect to the Symptoms and Feelings subscale, proving the psychological impact of the disease.

2. Cost-of-illness study

Population

Table 1 also shows the main socio-demographic and disease characteristics regarding the cost-of-illness study. The mean age of the 97 patients examined, 72 males (74%) and 25 females (26%), was 49.73 years. The majority (n=56, 60.8%) were employed, while 39.2% (n=38) were unemployed or retired. Also, the majority (n=84, 79%) were married, while 13.4% (n=13) were single, divorced or widow. The mean age at first diagnosis was 33.28 years. The mean PASI score was 20.17 and mean BSA score was 29.81%

Treatment pattern

Treatment patterns at baseline (Visit 1) are shown in Table 4. During the 3 months, the majority of patients received topical treatment (80%) and systemic therapy, non-biological (47%) or biological (52%). The number of hospitalizations and medical examinations is significantly high, involving 39 (40.2%) and 83 (85.6%) patients respectively.

Resource utilization and absence from work

The consumption of medical services and medications during the 3 months is shown in Table 5. The mean total cost per patient (direct health care cost plus loss of productivity) was €12,455.91 per year. Direct costs accounted for 95.7% of the total estimated disease costs for moderate and severe plaque psoriasis. The most significant direct costs pertained to biological medicines (77.97%) followed by hospitalization (9.8%), while costs due to topical or systemic non-biological therapy only accounted for 0.82% and 3.49% respectively.

The expenses incurred for psoriasis treatment were significantly higher in those patients treated with biological medicines than in patients that were treated without (Table 5).

The annual costs per patient that were treated without biological medicines amounted to € 3,856.85, while the costs per patient that was treated with biological medicines were € 25,244.26, which is >6.5 times more. The cost differences between these two groups of patients were predominantly due to the huge costs of biological medicines. The most significant cost to those patients that weren't treated with biological medicines was hospitalization which represented 48.61% of the total expenses. This was followed by the loss of productivity that represented 20.66% of the total expenses.

However, the prescriptions of biological medicines are associated with a statistical significant decrease in loss of productivity. Moreover, a non statistical significance reduction in ambulatory visits, diagnostic procedures and hospitalization, was noted. .

Table 1: Demographic and disease characteristics in moderate and severe psoriasis

	Quality of life study		Cost of illness study	
	N and/or %	SD	N and/or %	SD
N	177	-	97	-
Mean age in years	49.85	14.86	49.73	13.96
Sex (male)	119 (67%)	-	72 (74%)	-
Sex (female)	58 (33%)	-	25 (26%)	-
Mean age at first diagnosis (years)	33.16	16.23	33.28	15.63
Mean PASI at first visit	20.25	7.7	20.17	6.48
Mean BSA at first visit	29.8%	13.07	29.81%	11.62
Mean PASI at second visit	-	-	8.44	5.98
Mean BSA at second visit	-	-	14.89	8.78
Employed	99 (55.9%)	-	59 (60.8%)	-
Unemployed, Retired	78 (44.1%)	-	38 (39.2%)	-
Married	140 (79%)	-	84 (86.6%)	-
Single, divorced, widow	37 (21%)	-	13 (13.4%)	-

Table 2: SF36, Quality of life measurement at visit 1

	n=177	SD
Scales	Score	
Physical Functioning, PF	78,6	23,6
Role Physical, RP	77,3	36,1
Bodily Pain, BP	71	29,1
General Health, GH	52,4	22,3
Vitality, VT	65,1	19,7
Social Functioning, SF	80,7	25,7
Role Emotional, RE	77,4	39,8
Mental Health, MH	57	19,2
Physical Component Summary, PCS	47,9	-
Mental Component Summary, MCS	45,9	-

Table 3: DLQI means score and categories scores

Mean score	SD
6.07	6.18
Category	Score
Symptoms and feelings	35,8%
Daily activities	21,3%
Leisure	12,2%
Work and school	14,9%
Personal relationships	14,1%
Treatment	20,72%

Table 4: Treatment pattern during the 3 months

	N	%
Topic	78	80 (%)
Systemic (non-biological medicines)	46	47 (%)
Phototherapy	17	18 (%)
Non-conventional treatments (Homeopathy, Bach's flowers, Balneotherapy etc)	39	40 (%)
Biological medicines	39	40.2 (%)
<i>a Efalizumab</i>	<i>17</i>	<i>18 (%)</i>
<i>b Etenercept</i>	<i>17</i>	<i>18 (%)</i>
<i>c Infliximab</i>	<i>5</i>	<i>5 (%)</i>
Hospitalization	39	40.2 (%)
Medical examinations	83	85.6 (%)

Table 5: Direct health care and loss of productivity costs per year

	N=97			Non-biological medicines N=58		Biological medicines N=39	
	Total €	Per patient €	%	Per patient	%	Per patient	%
Direct health care cost	1.156.167,32	11.919,25	95,7	3059.88	79.34	25094.72	99.41
Hospitalization	118.000,00	1.216,49	9,8	1875.00	48.61	237.18	0.94
Ambulatory visits	4.540,00	46,80	0,4	43.66	1.13	51.49	0.20
Pharmacological treatment	994.110,24	10.248,56	82,3	736.15	19.09	24395.22	96.64
Topic	9.857,20	101,62	0,82	124.90	3.24	67.00	0.27
Systemic (non-biological)	42.160,12	434,64	3,49	611.25	15.85	171.99	0.68
Biological medicines	942.092,88	9.712,30	77,97	0	0	24156.23	95.69
Phototherapy	1.284,84	13,25	0,1	22.15	0.57	0	0
Laboratory examinations	26.032,24	268,37	2,2	251.89	6.53	117.95	0.47
Non-conventional treatments	12.200,00	125,77	1	131.03	3.40	292.89	1.16
Loss of productivity	52.056,00	536,66	4,3	796.97	20.66	149.54	0.59
Total cost	1.208.223,32	12.455,91	100	3856.85	100	25244.26	100

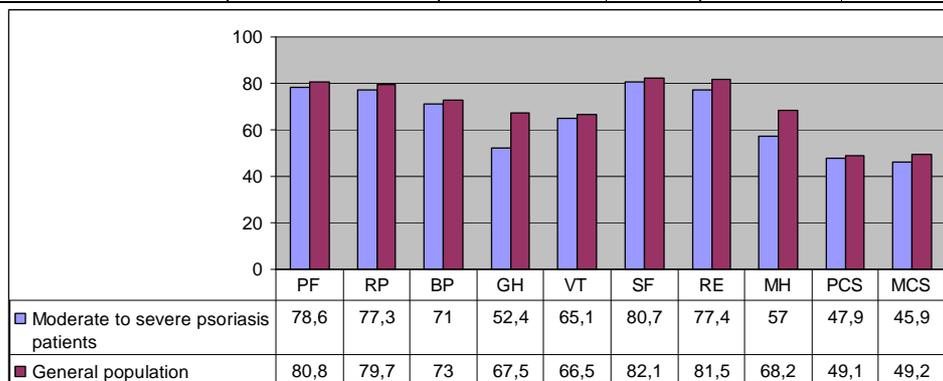


Figure 1: SF36: Quality of life measurements at visit I compared to the mean for the Greek population¹⁰

Effectiveness of the treatment

The patients that enrolled in the study during the 1st visit were found to have a mean score of PASI: 20.17 and BSA: 29.81%. Despite the treatment used, being the conventional methods (topic medicines, phototherapy and systemic but non biological medicines, such as cyclosporine and methotrexate) or with the introduction of biological medicines, clinical results were successful. During the patients' 2nd visit, 3-months later, the mean PASI and BSA scores were 8.44 and 14.89% respectively. Specifically, 67 out of the 97 patients (69.1%) achieved a PASI 50 (which means 50% improvement of the PASI index), whereas 37 of them (38.1%) achieved a PASI 75 (which means 75% improvement of PASI index).

Discussion

Plaque psoriasis is a very common cutaneous disease which may have a profound impact on the affected person's QoL and a substantial economic impact for the patients and the health care system. In spite of this, only a few studies have been performed with little attention to presenting an overall picture of the costs of care for patients with psoriasis, especially after the induction of biological medicines in the treatment of the illness. This also applies to Greece, where little is known about the epidemiology, the patients' quality of life and the economics of psoriasis.

According to our study on the quality of life and the cost of illness of moderate and severe plaque psoriasis in Greece:

1. Moderate and severe plaque psoriasis negatively affects the patients' quality of life in every aspect examined compared with the population at large (Figure 1).
2. Moderate and severe plaque psoriasis represents an important cause of economic burden in Greece. Direct health care costs are higher than loss of productivity cost. Biological medicines are the most significant item, accounting for 77.97% of total expenses. For those that weren't treated with biological medicines, the most significant item was hospitalization, accounting for 48.61% of their total expenses.
3. Despite the treatment used, being the conventional methods (topical medicines, phototherapy and systemic but non biological medicines) or with the introduction of biological medicines, clinical results were successful.

Psoriasis causes significant psychosocial problems, as the results of the SF36 and DLQI questionnaires from this study show, which means that improvement in the quality of life, should be a major

issue in economic considerations. Skin diseases can substantially diminish QoL, restricting work, social, and family relationships. Patients may find skin diseases more disabling than other diseases that are usually considered more serious, as they often feel that the disease alters their lives far more adversely than patients with cancer, diabetes or heart failure (Rapp SR et al, 1999).

The annual costs calculated for a patient with moderate plaque psoriasis in Greece amounted to €12,455.91 per year whereas the costs for a patient that were not treated with biological medicines were €3,856.85. An Italian Cost-of-illness study (Colombo GL et al, 2008), found that the annual costs per patient was €5,226.04 with a mean PASI score of 21.4 while a German Cost-of-Illness study (Sohn S. et al 2006), showed a total annual cost per treated patient of €6,709.00, with a mean PASI score of 18.2. Both studies were performed before the induction of biological medicines in the treatment of the disease. Both aforementioned studies, found direct costs higher than indirect costs and that hospitalization was the most significant item contributing to the total cost. The above findings correlate with our study results among the patient group that was not treated with biological medicines.

Limitations

A number of limitations of our study are well noting. First, we extrapolate the 3-month expenses to 1 year in order to be able to do comparisons with similar studies. Furthermore, not all the cost items, such as out-of-pocket expenses e.g. for transportation, were included in the study. Finally, we used the human capital approach in calculating the loss of productivity in the form of overall productivity losses which may underestimate it. Additionally, the above approach may seem discriminating against people with no market value such as the unemployed, retired people, and housewives.

Conclusions

Plaque psoriasis has a profound impact on the affected person's QoL and is associated with extremely high costs. With the advent of the biological medicines psoriasis costs become even higher. However, the prescriptions of biological medicines are associated with a decrease in loss of productivity. Strictest compliance with the disease management guidelines as well as introduction of generic biologicals medicines will significantly mitigate the increasing cost of this chronic disease.

Finally, we deem that our study findings provides important data for further decision making, as it

deals especially with the economic assessment of innovative therapies for moderate and severe plaque psoriasis. Further outcome data over a long time frame are needed for better informed decisions in health technology assessment.

Conflict of interest

The authors declare that they have no financial and/or other relationships that may lead to a conflict of interest.

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