

# ASSESSMENT OF THE LIFE QUALITY OF THE PATIENTS WITH SEVERE PSORIASIS, BEFORE AND AFTER THE BIOLOGICAL THERAPY

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**Keywords:** psoriasis, life quality, biological treatment, DLQI (Dermatological Life Quality Index) score, PASI (Psoriasis Area Severity Index) score

**Abstract:** Psoriasis is a chronic disease that greatly influences economy and the daily life of the patients. The patients diagnosed with psoriasis live with a profound individual discomfort that is reflected on the relational life. From the esthetic point of view, or from the point of view of the appearance of the disease, we must take into account two points of view: the perception of the patient concerning this issue within the relationship with himself and with the persons he cares for and the perception the others have about the disease (many fear that the disease is contagious). For this purpose, the duty of the specialist is not only to identify the adequate therapy of the patient, but also to support him in the “social” management of the disease. However, the cutaneous impairment can be rapidly ameliorated by means of an adequate treatment. We consider that a revolutionary treatment, such as the biological therapy has a potential positive impact on the quality of life and on improving the disease severity.(1)

**Cuvinte cheie:** psoriazis, calitatea vieții, tratament biologic, scorul DLQI (Dermatological Life Quality Index), scorul PASI (Psoriasis Area Severity Index)

**Rezumat:** Psoriazul este o boală cronică cu un impact puternic atât asupra economiei cât și asupra vieții cotidiene a pacienților. Pacienții diagnosticați cu psoriazis trăiesc un profund disconfort individual, care se reflectă mai ales asupra vieții relaționale. Din punct de vedere estetic, sau mai bine spus al vizibilității bolii, trebuie luate în considerare două aspecte: percepția pacientului cu privire la această problemă în relație cu el însuși și cu persoanele care-i sunt apropiate și percepția pe care o au ceilalți despre boală (mulți se tem că este contagioasă). În acest sens, sarcina specialistului nu este doar aceea de a identifica terapia adecvată pacientului, ci și de a-l sprijini în managementul „social” al bolii. În același timp însă, afectarea cutanată poate fi rapid ameliorată cu ajutorul tratamentului potrivit. Apreciem că un tratament revoluționar, așa cum este terapia biologică, are un impact potențial pozitiv asupra calității vieții și ameliorării severității bolii.(1)

## INTRODUCTION

In the last twenty years, the doctors and the researchers had at their disposal life quality measuring instruments regarding the patients suffering of psoriasis. The psychometric scales, under the form of questionnaires, explore different aspects of the patients' life, such as the daily activities, social relationships and the self image. The scales of the life quality are rarely used by the dermatologists in the medical current practice. However, the researchers frequently use them in order to evaluate the influence of the clinical features of psoriasis (severity and place of the lesions) on the quality of life.(1,2)

The World Health Organization defines the quality of life in the following manner: “the perception that a person has on the place he occupies in the cultural system context and of the values where he lives in and concerning his objectives, expectations and concerns.” The quality of life is appropriate when the expectations of a person correspond to the reality.(2) Psoriasis has an impact on all the aspects of life, affecting the career of the patients, the social and sexual relationships and the family life. On these grounds, it is essential that the treatment takes into account the life quality, this thing representing the key of the doctor – patient relationship. Even though the doctors have taken into account this aspect until now, the present patients have access to a higher level of information, especially

due to mass-media, and consequently they have higher expectations regarding their treatment.(3) When the patients are not satisfied with the quality of their life, it means that they are not satisfied with the treatment. The therapeutic strategies do not sufficiently take into account the patient's life quality. Additionally, the fact that the patient undertakes more treatments means imposing important constraints on the patients.(4) In order to find a solution of completely cure the disease, the patients suffering of psoriasis may tend to believe in all kind of “miraculous treatments”. However, no treatment on the market, at present, can cure psoriasis; these only maintain the disease under control. Actually, the modern biological therapies tend to revolutionize the treatment of modern and severe psoriasis, providing certain advantages, such as the lack of toxicity on the internal organs, improving the quality of life or inducing a sustained remission but, unfortunately, the biological therapies do not cure the disease.(5,6)

## PURPOSE

The aim of the study is to comparatively assess the impact of drug therapies on the quality of life of the patients suffering from severe psoriasis.

## METHODS

The target population of this paper is represented by the patients suffering from chronic psoriasis (medium or severe

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form) who received the initiation approval of the treatment with biological agents from the CNAS (National Health Insurance House) board of experts for approving the treatment of chronic psoriasis with biologic agents, during the period January 01<sup>st</sup> 2009 – March 31<sup>st</sup> 2009. The research period was between January 2009 and June 2010 (18 months).

410 patients who observed the eligibility criteria for the biological therapy, according to the provisions of „the Therapeutic Protocol concerning the treatment with biological medicines of the chronic psoriasis (mild or severe form)”, approved by the Order of the Ministry of Health and of the president of CNAS no. 1301/500/2008 concerning the approval of the therapeutic protocols concerning the prescription of the medicines afferent to the international common names corresponding to the medicines that insured persons benefit from, with or without a personal contribution, on grounds of a medical prescription, in the social security system, approved by the Decision of the Government no. 720/2008, with the subsequent modifications and amendments.(7)

The research is based on a crossover trial that emphasizes the standard therapy aspects and the biological therapy in mild /severe psoriasis, correlated to the quality of the life's patients. Its assessment was made according to the DLQI – Dermatological Life Quality Index score, which was drafted by Prof. A. Finlay from Great Britain and according to the PASI - Psoriasis Area Severity Index score, who used in the classification of the severity of psoriasis, a clinical indicator that estimates the surface of the affected tegument.(8)

The impact was studied according to different medicine approaches (adalimumab, etanercept or infliximab) on the quality of the pre and post therapy, respectively the effect on certain parameters of the health state (pain, itching, damaged area, common activities, depression, self care, improvement of the DQLI and PASI scores). The assessment by means of these instruments was made before the initiation of the biological therapy and after its initiation, firstly at intervals of 3 months, afterwards at intervals of six months.(9,10)

### RESULTS AND DISCUSSIONS

Life's quality represented the basic criteria of study of our study pattern. Its evaluation was achieved according to life quality depreciation score DLQI – Dermatological Life Quality Index. As the score was higher, the life quality was more affected by the disease. The DLQI score between 21-30 signifies an important effect on the life quality of the patient.

The studied population was represented by 410 persons diagnosed with chronic psoriasis who benefited from biological therapy, coming from the urban and rural environments, significantly more males, with a higher frequency of the patients having an active age. In what concerns the territorial distribution, the accessibility of the patients to the biological therapies is associated to the presence of the specialist dermatologists. We mention that of the 410 studied patients only 371 came back in 3 months for the DQLI and PASI score, 353 in 6 months, 284 in 12 months and 179 in 18 months.

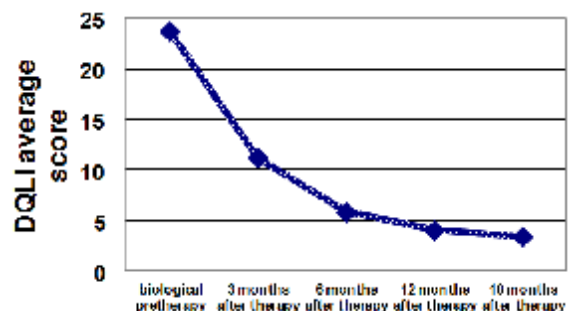
The post-therapy data with biological agents in 3 months suggest that the intervention represents an efficient treatment method for the severe psoriasis. Consequently, according to the average DQLI index, there was registered an improvement of 53% (by 12,57). For the evaluation of the efficiency of the treatment by means of biological therapies, we used the Anova test with repeated measurements for analysing the significance of the differences found by means of the DQLI score.(11,12,13) However, we must mention that we could test only the 179 patients who attended the five moments of the surveillance. The one-dimensional variance measurement

indicated a significant effect of the biological treatment in the 5<sup>th</sup> moments. The Mauchly sphericity test is significant, respectively the sphericity condition is not assumed and we must adjust the significance levels of the test. Consequently, we use the Greenhouse – Geisser test, for which the significance of the F report is lower than 0,001.

The evaluation of the pre-therapy life quality versus the biological post-therapy, according to the DQLI score, shows an increasing improvement in the 4 moments after the initiation of the therapy, reaching 86% at the end of the surveillance period (18 months). In three months since the initiation of the treatment, the quality of the life increases in the case of most of the patients. In 6 months since the initiation of the biological treatment, the results are similar to the ones from the 18 month-post-therapy. The DQLI index is the most important effect in 3 months since the initiation of the biological therapy. Furthermore, the effect is maintained but the quality of the patient's life does not ameliorate in the subsequent examinations. Most of the examined patients showed a very important effect on the quality of their lives, the entire patient's life quality was affected.

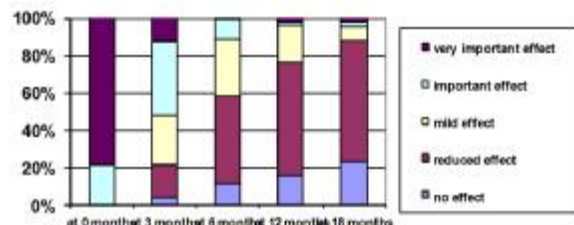
The evaluation of the quality of the pre-therapy life versus the biological post therapy, according to the DQLI score, shows an improvement of 53% at 3 months, 75,5% at 6 months, 83% at 12 months and one of 86% at the end of the surveillance period (18 months) (figure no. 1).

**Figure no. 1. The evolution of the averages of the DQLI score pre- and post- biological therapy during the period of the 18 months of examining the study pattern**



The DQLI score has the most important effect at 3 months since the initiation of the biological therapy initiation. Afterwards, the effect is maintained but the quality of the patient's life does not ameliorate at the subsequent examinations (figure no. 2).

**Figure no. 2. Evaluation of the biological therapy effect according to the DQLI index in the study pattern**



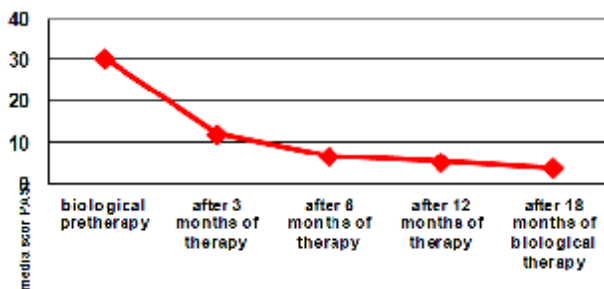
The PASI score varied from 0 to 70. (PASI ≤ 3: indicates a low psoriasis, 3 < PASI ≤ 10: moderate psoriasis, 10 < PASI: severe psoriasis). The average of the PASI score in the initiation moment of the biological therapy was of 31,81 (SD = 11,16), minimum 0 and maximum 70, module of 32,4, median of 30,3. The post-therapy data with biological agents in 3

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months suggest that the intervention represents an efficient treatment manner for the severe psoriasis. The one-dimensional variance analysis sphericity test is significant, respectively the sphericity condition is not assumed and we must adjust the significance levels of the analysis. This is why we use the Greenhouse – Geisser test, for which the significance of the F report is lower than 0,001. Following the evolution of the severity of psoriasis, measured by means of the PASI score at the study pattern, we noticed its improvement, after the initiation of the biological therapy, by 63% in 3 months, by 78% in 6 months, by 83% in 12 months, by 87% in 18 months (figure no. 3).

According to the PASI score, we may evaluate the severity of psoriasis. At the initiation of the biological treatment, of the total number of 410 patients, only one suffered from mild psoriasis and one from low psoriasis. In three months since the initiation of the therapy, of the 375 assessed patients, 11% had low psoriasis, 30% mild psoriasis and only 59% had severe psoriasis. From the point of view of the evolution of the severity of the psoriasis, the proportion of the severe form decreased at 5% in 18 months from the initiation of the treatment.

**Figure no. 3. Evolutions of the PASI biological pre- and post-therapy score averages during the 18 months of surveillance of the study pattern**

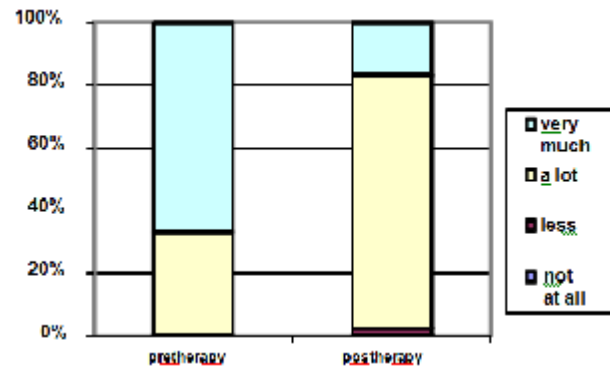


The PASI score ameliorates significantly after 3 months of immunologic therapy both for the entire study pattern and also for those who needed switches. The issues appear in 12 months from the initiation of the treatment, when we notice a severe decrease of the PASI score in the ones who needed the change of the biological treatment medicines. The DQLI score has the same tendencies, but it is not severe, in what concerns its values even since the 6<sup>th</sup> month of biological treatment by maximum 12 months.

The cases that in 6 months from the initiation of the biological treatment initiation have no result will not register improvements in 18 months. The subjective indicators of measuring the quality of life (DQLI score) can represent a precocious alarm signal, that emphasises the change need of the immunologic treatment and that appears 6 months before the modification of the clinical disease signs that were measured by means of the PASI score.

The analysis of the life quality after the initiation of the biological therapy at the level of the high intension pain and discomfort (itching, stiches or injuries at the level of the skin), showed an amelioration by 73% versus the biological pre-treatment, mentioning that after the initiation, the weight of those accusing moderated pains increased from 33% to 89,5% and the percentage of those who accused itches, stiches, great pain decreased from 67% to 18 % (figure no. 4).

**Figure no. 4. Evaluation of the pain and discomfort, pre- and post- initiation of the therapy on the study pattern**



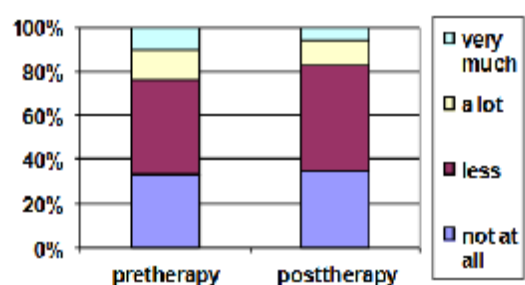
The assessment of the quality of life before the biological therapy versus the post-initiation of the treatment, according to the embarrassment feeling of the patient in the study pattern, showed an improvement of the physical condition, at 3 months a high and a high affectation decreased from 98% to 68,5%, respectively ameliorated by 30%. We analysed the cases from the point of view of the interference of the skin disease with shopping, with the household activities and with gardening, before the treatment and 3 months after the biological therapy. Our study showed an improvement by 42% (from 89% high affection and very high pre-therapy by 37% after 3 months since the initiation of the therapy) of the household activities after the initiation of the biological therapy.

It was also studied the issue of choosing the clothes before and after the initiation of the treatment, in 3 months of treatment with biological medicines. The data showed also in this case an improvement by 16% (from 97% to 81%). The analysis of the quality of the life after the initiation of the biological therapy from the point of view of the very high and high affection, of the entertainment and of the social activities, showed an amelioration by 62% versus the biological pre-treatment (from 97% to 35%).

The evaluation of the quality of life before the biological therapy versus the post-initiation of the treatment, according to the affection of a sport at the study pattern showed an improvement of the life style, in 3 months – the high and great affection decreased from 65% to 19% respectively, ameliorating by 71%.

The interference of the disease in the relationship with the partner manifested by sexual difficulties severely affected the life quality of our study pattern. We noticed an improvement of the sexual life, after the initiation of the immunologic treatment in the first 3 months, by 7% in those accusing a very high or high affection (figure no. 5).

**Figure no. 5. Evaluation of the sexual life affectation, before and after the initiation of the therapy, on the study pattern**



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By processing the data obtained by means of the dermatological enquiry concerning the quality of life of the DQLI patients, in 3, 6, 12 and 18 months from the initiation of the biological treatment, it was emphasised a significant improvement of psoriasis, respectively: 68% of the patients presented embarrassment feelings at the initiation of the immunological treatment, caused by the lesion, experiencing during the research period a significant amelioration, up to 7,6% of the questioned persons invoked the embarrassment feeling for 18 months.

If before the initiation of the biologic therapy, 54% of the patients suffering from chronic psoriasis felt an alteration of the quality of life because of the reduction of the household activities that they were able to carry on, in 18 months from the initiation of the treatment, only 3,9% of the patients presented this issue.

The fact that the patients had to undergo treatments for the chronic psoriasis affected, before the biologic therapy, almost half of the persons attending the research. In 18 months since the initiation of the treatment with biological agents, only 16% of the patients considered that the quality of their lives was affected by the repetition of the treatments for the researched disease.

The effective study on the biological therapy in chronic psoriasis showed an efficient amelioration by 5 units for the DQLI and over 50% for the PASI after 3 months of immunological therapy. At 18 months since the initiation of the biological therapy it is remarked a decrease of the average values of the PASI and DQLI scores up to approximately equal values. There is a statistically significant correlation of the PASI score and the values of the DQLI score at the 0 moment, in 3 months, in 6 months, in 12 months and in 18 months.

## CONCLUSIONS

In psoriasis, additionally to the management of the disease or of a „case”, we must achieve the management of the patient. The appreciation indicators of the severity of the psoriatic disease (PASI score) and of the damage on the quality of the life of the patients suffering from psoriasis (DQLI score) are very useful in the clinical practice, representing concrete criteria, that allow the choice of certain adequate therapy and an adequate surveillance of the evolution of the disease.

The immunologic therapy (biological) in the severe psoriasis represents an alternative to the classical therapies and it has clinical and psychosocial and somatic effects that can be evaluated in only 3 months of treatment. We ascertained an amelioration of the pain, of the self-care, of the entertainment and of the different social activities that had been affected. The analysis of the quality of life after the biological therapy from the point of view of the discomfort (itches, stitches or injuries at the level of the skin) of a great intensity, showed an amelioration versus the biological pre-treatment, mentioning that after initiation, the weight of those accusing moderate pains increased and the percentage of those accusing itches, stitches and great pain decreased.

It was emphasised an improvement of the psychical condition, and also an improvement of the household activities after the initiation of the biological therapy and an amelioration from the point of view of the interference of the disease with the activities of shopping, household activities, gardening activities. The assessment of the quality of life according to the criteria concerning the practicing of a sport, of choosing the clothes, showed the improvement of the life style. The interference of the disease in the relationship with the partner, manifested by sexual difficulties severely affected the quality of life, and after

the initiation of the immunological treatment in the first 3 months, we noticed an improvement of the sexual life.

The initiation of a systematic strategy of supporting the management of the patient shall increase the interest of the patient in insuring the continuity of the medical activity up to the compliance of the patient to the administrated biological therapies.

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