Original article

The Impact of Biological Therapy on Health-Related Quality of Life in Patients with Psoriasis

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SUMMARY

Introduction/Aim. Psoriasis is a chronic, relapsing, non-infectious dermatosis, affecting patients` quality of life. There is still insufficient evidence from routine clinical practice on how the biological therapy improves the quality of life of patients with psoriasis. The aim of our study was to examine the effectiveness of biological therapy, regardless of the drug type, on health-related quality of life (HRQoL) in patients with psoriasis.
Methods. We performed a prospective observational pilot study at the Clinic of Dermatovenerology, University Clinical Center Niš in the period from from October 1, 2019 to March 1, 2020. The study involved 29 patients with psoriasis vulgaris (11 females, 18 males) on biological therapeutics regardless of the type of the drug. The severity of psoriatic lesions and the patient's response to treatment was assessed using the Psoriasis Area and Severity Index (PASI) before the treatment with secukinumab and ustekinumab and after 10 weeks. Dermatology Life Quality Index (DLQI) was determined at the beginning of biological treatment as well as after 10 weeks.
Results. The average age of participants was 49.69 ± 12.75 years and the sample consisted mainly of men (62.1%). The average disease duration among men was 16.44 ± 10.05 years, and among women 17.82 ± 12.79 years. The mean DLQI decreased from 15.62 ± 7.79 to 6.34 ± 7.19 after biological treatment. The initial mean PASI and DLQI scores differed significantly from the average control scores (t-test for paired samples, $p < 0.0001$).
Conclusion. Biological therapies of psoriasis, in addition to improving the clinical picture, demonstrated an improvement in the patients' HRQoL very quickly and they should be considered during evaluating the benefits and risks of this type of therapy.

Keywords: psoriasis, biological treatment, quality of life

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INTRODUCTION

Psoriasis is relapsing, non-infectious dermatosis mediated by immune cells, of a chronic course with remissions and exacerbations, which represents a significant burden for patients, their families and society. It is systemic inflammation associated with metabolic, arthritic, psychological and cardiovascular comorbidities.

Psoriasis occurs more frequently in adults than in children, while it is more often expressed in countries with higher economic standards. The prevalence of psoriasis in children varies from 0.02% in East Asia to 0.21% in the western part of Europe, while the prevalence of this disease in adults ranges from 0.14% in East Asia to 6.60% in Australia (1).

The etiology of psoriasis has not been precisely determined so far, while its pathogenesis is multifactorial. The clinical picture of patients with psoriasis can vary from minimal and localized lesions without subjective symptoms, over inflammatory, pruritic and painful, clinically visible lesions to life-threatening conditions.

Psoriasis therapies are currently numerous and varied. The individual approach is of great importance for the effective treatment of psoriasis (4).

Nowadays, there is a large number of biological drugs that are used in the therapy of psoriasis. Two biological drugs for the treatment of psoriasis are used at the Clinic of Dermatovenerology, University Clinical Centar Niš: secukinumab (a human IgG1κ monoclonal antibody that specifically targets interleukin-17 (IL-17) and ustekinumab (a drug with a monoclonal antibody that binds to two mentioned molecules – interleukin 12 and interleukin 23).

The impact of psoriasis on the life of affected patients is great, which is the case as with other chronic diseases (6, 7). Psoriasis patients are more likely to be depressed and with difficulties at the workplace because of psoriatic arthritis and other comorbidities (8, 9).

To assess the activity of the psoriasis and how it affects the patient's quality of life in clinical practice, wider evaluations are necessary to determine the degree of the disease and how patients respond to therapy. Previous results have shown that biologics and conventional systemics were effective in real-life treatment of psoriasis, with as many as 75% of patients having an improvement in their clinical picture. The scores indicating the severity of psoriasis were significantly lower after the application of systemic therapy compared to the classical one (11, 12). A larger number of clinical studies on the effectiveness of biological therapy on patients' quality of life are lacking.

AIM

The aim of our study was to examine the effectiveness of biological therapy on health-related quality of life (HRQoL) among patients with psoriasis, regardless of the drug type.

PATIENTS AND METHODS

We performed a prospective observational pilot study at the Clinic of Dermatovenerology, University Clinical Center Niš, in the period from October 1, 2019 to March 1, 2020.

Patients

The study involved 29 patients with psoriasis vulgaris (11 women, 18 men) treated at the Clinic. Most patients (27 or 93.1%) had lesions located on the exposed parts of the body (face, neck, head, hands). Patients were treated with phototherapy and topical ointments, without biological methods before the start of the study. Patients were informed about the objectives and gave informed consent to participate in the study. The study complied with the Declaration of the World Medical Association from Helsinki.

Methods

At the beginning, demographic data (participant gender, age, smoking habits, etc.) and data on medical history, previous psoriasis therapy and duration and course of the disease were recorded. Patient screening was performed after 10 weeks.

Disease severity was assessed using the PASI as mean ± SD before starting treatment and after 10 weeks.

The health status was assessed through self-reported outcomes using the Dermatological Quality of Life Index (DLQI) at the start of biologic treatment and after 10 weeks. The DLQI questionnaire has 10 questions that assess the impact of skin disease on the six aspects of HRQoL: symptoms and feelings, daily activities, leisure time, work or school performance, personal relationships, and treatment (13,

14). The total score ranges from 0 to 30, with a score of 0 – 1 indicating no HRQoL damage and higher scores indicating greater damage (15). A reduction of ≥ 4 points is clinically significant (16).

Statistical analyses

The results were statistically processed using the standard software SPSS version 20.0 (IBM Corp, Armonk, NI, USA). The results of the study were tabulated by estimating the mean [± standard deviation (SD)] and median (range). The independent samples t-test was performed to compare the means. $p < 0.05$ was considered statistically significant.

RESULTS

The majority of the sample consisted of men (62.1%). The mean age of male patients was 46.89 ± 12.45 years, and the mean age of female patients was 52.36 ± 13.90 years. There were no statistically significant differences in the mean age between the two gender groups (t-test: -1,1; $p > 0.05$). Moreover, no gender-related statistically significant differences in the disease duration were found (Mann-Whitney test, $p > 0.05$): the average disease duration among men was 16.44 ± 10.05 years, and 17.82 ± 12.79 years among women.

The main characteristics of the participants are shown in Table 1. There were no statistically significant differences in the place of living between the two gender groups: χ^2 test (0.184, $p > 0.05$) and Fisher test (0.717, $p > 0.05$), also between the smoking habits (χ^2 test: 1.266, $p > 0.05$) and presence of other diseases (χ^2 test: 3.157, $p > 0.05$).

Significant improvements in clinical sense were achieved within 10 weeks of treatment. Average PASI score before the treatment with biological agents was 18.07 ± 11.381, and 5.73 ± 8.457 after 10 weeks with biological therapy (PASI 75).

Table 1. *Patient characteristics*

Item	Male	Female	Significance
Place of living			
Urban	10 (55.6%)	7 (63.6%)	$p > 0.05$
Rural	8 (44.4%)	4 (36.4%)	$p > 0.05$
Smoking			
Yes	12 (66.7%)	5 (45.5%)	
No	6 (33.3%)	6 (54.5%)	
Comorbidities			
Yes	14 (77.8%)	5 (45.5%)	$p > 0.05$
No	4 (22.2%)	6 (54.5%)	$p > 0.05$

Significant improvement in DLQI was also seen within 10 weeks of biological treatment. Namely, at the beginning, the DLQI score was 15.62 ± 7.789, and 6.34 ± 7.193 after ten weeks, with a statistically significant lower value, $p < 0.001$ (Table 2).

Table 2. *Dermatology Life Quality Index (DLQI) total average scores in psoriasis patients*

Parameter	Mean ± SD
DLQI at the beginning of treatment	15.62 ± 7.789
DLQI after 10 weeks	6.34 ± 7.193

*$p < 0.001$

Table 3 reported PASI and DLQI data at baseline and at 10 weeks following the treatment. The difference in DLQI scores were statistically significant at the beginning and after 10 weeks of biological therapy.

When mean reduction in PASI was plotted against mean reduction in DLQI, a correlation coefficient value of 0.538 was observed ($p < 0.001$). Also, the baseline PASI correlated with the baseline DLQI; control PASI after 10 weeks with biological therapy correlated with control DLQI (Table 4).

Table 3. *PASI and DLQI data differences*

Variable Paired differences	X ± SD	Standard error	95% confidence Interval (lower-upper)	t-test for paired samples	P value
PASI at the beginning - control PASI	12.345 ± 11.57	2.149	7.944 - 16.746	5.746	< 0.0001
DLQI at the beginning - control DLQI	9.276 ± 6.974	1.295	6.623 - 11.929	7.163	< 0.0001

Table 4. *Correlation between PASI and DLQI scores of participants*

Correlation		Baseline PASI	Baseline DLQI	Control PASI	Control DLQI
Baseline PASI	Pearson's correlation	1	.475**	.349	.053
	significance		.009	.064	.783
Baseline DLQI	Pearson's correlation	.475**	1	.131	.569**
	significance	.009		.498	.001
Control PASI	Pearson's correlation	.349	.131	1	.538**
	significance	.064	.498		.003
Control DLQI	Pearson's correlation	.053	.569**	.538**	1
	significance	.783	.001	.003	

**statistically significant

DISCUSSION

Although psoriasis generally does not affect survival, it certainly has a huge negative impact on the physical, emotional, and psychosocial wellbeing of the affected patients, demonstrable by a significant detriment to quality of life. This pilot study showed that the applied biologic therapies for psoriasis (regardless of the type of the drug) were associated with significant clinical and HRQoL improvements over 2.5 months.

Our results are similar to those of other authors (17,18). In an Australian study with 65 psoriatic patients, at week 14, the mean reduction in the total DLQI score from the baseline was 82.4%, indicating a significant improvement in quality of life. Treatment with secukinumab showed an impressive improvement in the quality of life in patients with severe form of the disease (19). Re-

searchers from Great Britain studied more than 2,000 patients and showed that biological therapies lead to a significant improvement in HRQoL, depending on the type of biological therapy effects, basic HRQoL damage, lifestyle habits and comorbidities (20). A study from Switzerland with 334 randomly selected patients shows that biological drugs after one year of using contributed to an improvement in the subjective course of the disease compared to conventional systemic therapy (21). Also, after ten years of monitoring almost 600 patients with psoriasis in Sweden, it was found that biological treatment showed a significant improvement in quality of life and longer lasting effects of PASI and DLQI (22).

The shortcomings of our research are the small sample size of the study, no standardized criteria for determining the time to visit a new physician when calling the clinic, and variation in physician experience.

Measurement of HRQoL in clinical practice requires the use of simple questionnaires that can be completed quickly, which provides information that is both reliable and valid. Dermatology Life Quality Index (DLQI) is the most commonly used quality of life instrument in dermatology practice. Quality of life is not easy to understand and requires inter-disciplinary research that explores many aspects of disease. Psoriasis globally is not connected with the length of life, but it has a significant impact on quality of life, which is the case with other non-communicable diseases.

Today, the dermatological quality of life index is increasingly recommended for use in health-care practice and provides useful data about the impact of psoriasis on the patient's daily life. Examining the quality of life and possibilities for its improvement is extremely important considering the increase in life expectancy and increase in the frequency of chronic non-communicable diseases, such as psoriasis, with which many patients are forced to live. On the basis of clinical examinations, important information is obtained about the state of the affected organ, but they rarely indicate the functional disorders caused by the disease, which are of great importance for patients in their daily life. Accordingly, it is im-

portant to examine the quality of life of patients and thus enable the inclusion of the patient's attitude in the assessment of their health condition in order to enable patients to feel better and function in daily activities.

CONCLUSION

To conclude, patients with psoriasis on biological treatment demonstrated an improvement in HRQoL very quickly, which should be considered during evaluating the benefits and risks of this type of therapy.

Acknowledgment

Conflicts of interest

None.

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Uticaj biološke terapije na poboljšanje kvaliteta života bolesnika sa psorijazom

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SAŽETAK

Uvod/cilj. Psorijaza je hronična zapaljenjska recidivirajuća neinfektivna dermatoza, koja utiče na kvalitet života bolesnika. Još uvek nema dovoljno dokaza iz kliničke prakse o efektu koji biološka terapija korišćena u lečenju psorijaze, bez obzira na vrstu biološkog leka, ima na kvalitet života obolelih. Cilj rada bio je ispitati uticaj biološke terapije na kvalitet života bolesnika sa psorijazom.

Metode. Sprovedena je prospektivna opservaciona studija na Klinici za dermatovenerologiju Univerzitetskog kliničkog centra Niš u periodu od 1. oktobra 2019. do 1. marta 2020. godine. Ispitano je 29 bolesnika sa psorijazom (11 žena i 18 muškaraca) na biološkoj terapiji; pritom, vrsta biološkog leka nije bila relevantna. Klinička slika bolesti procenjena je upotrebom indeksa *Psoriasis Area and Severity Index* (PASI) kao srednja vrednost ± SD pre lečenja lekovima secukinumab i ustekinumab i nakon deset nedelja od terapije. Dermatološki indeks kvaliteta života određen je na početku lečenja i nakon deset nedelja.

Rezultati. Prosečan uzrast ispitanika bio je 49,69 ± 12,75 godina i u njemu su preovladavali muškarci (62,1%). Prosečno trajanje bolesti kod muškaraca bilo je 16,44 ± 10,05 godina, a kod žena 17,82 ± 12,79 godina. Prosečna vrednost DLQI pala je sa 15,62 ± 7,79 na 6,34 ± 7,19 nakon uzimanja biološke terapije. Prosečni skorovi PASI i DLQI značajno su se razlikovali pre i posle sprovođenja terapije (T-test: $p < 0,0001$).

Zaključak. Biološka terapija psorijaze, osim što popravlja kliničku sliku, značajno i brzo poboljšava kvalitet života bolesnika, što treba uzeti u obzir prilikom evaluacije njenih prednosti i rizika.

Ključne reči: psorijaza, biološka terapija, kvalitet života