

3

## Determining disease severity

Hastalık şiddetinin tanımlanması

## Emel Bülbül Başkan

Uludağ University Faculty of Medicine, Department of Dermatology and Venereology, Bursa, Turkey

#### Abstract

Assessment of the severity of psoriasis is versatile, and unfortunately, there is no single tool that can assess the severity of this disease in every aspect. As well as psoriasis area and severity index, other tools such as physician's global assessment and body surface area are also used in assessing the severity of psoriasis. The index used to assess quality of life is the dermatology life quality index. This section discusses the methods used in determining the severity of psoriasis, descriptions of treatment phases and goals, and measurement of treatment success. **Keywords:** PASI, PGA, BSA, DLQI

#### Öz

Psoriasis şiddetinin değerlendirilmesi çok yönlüdür ve maalesef hastalığın şiddetini her yönüyle belirleyebilen bir araç yoktur. Psoriasis şiddetinin belirlenmesinde psoriasis alan şiddet indeksi yanında, doktorun global değerlendirmesi ve vücut yüzey alanı da kullanılmaktadır. Yaşam kalitesini değerlendirmede kullanılan indeks ise dermatoloji yaşam kalite indeksidir. Bu bölümde psoriasis şiddetinin belirlenme yöntemleri yanında, tedavi fazlarının ve hedeflerinin tanımlanması ve tedavi başarısının belirlenmesi de değerlendirilmektedir. **Anahtar Kelimeler:** PAŞİ, DGD, VYA, DYKİ

#### Introduction

Assessment of the severity of psoriasis is multidirectional and unfortunately there is no single tool that can assess the severity of this disease in every aspect<sup>1</sup>. Authors of guidelines share for this purpose their proposals structured within a consensus on the basis of literature data, similar guidelines, and their own experiences. One of the most widely used scales to determine the severity of psoriasis is the psoriasis area and severity index (PASI), which rates the symptoms of the disease such as erythema, dandruff and induration/infiltration by their anatomic localizations. PASI is a reliable and repeatable scoring method for adult patch-type psoriasis<sup>1,2</sup>. Another scale frequently used to assess disease severity is the physician's global assessment of disease activity (PGA). Rated in 5, 6, 7 steps from clear to very severe, PGA can be used to measure recovery (dynamic PGA) and it can also be used to determine disease severity in a certain time frame (static PGA). PGA, which has been shown in clinical studies to have a correlation with PASI, may be preferred in daily practice as it is an easier and more practical scale<sup>3,4</sup>. Showing the % distribution of involved areas, body surface area (BSA) is another simple scale that can be used when PASI is inapplicable.

Psoriasis is a chronic disease that may have negative effects on many areas from social stigmatization to physical constraints and emotional disorders. For this reason, when determining the severity of psoriasis, scales that allow patients to evaluate the effect of the disease on their quality of life should also be employed. One of such scales used and accepted most

Address for Correspondence/Yazışma Adresi: Emel Bülbül Başkan MD, Uludağ University Faculty of Medicine, Department of Dermatology and Venereology, Bursa, Turkey

> E-mail: emelbulbulbaskan@gmail.com Received/Geliş Tarihi: 07.02.2022 Accepted/Kabul Tarihi: 11.02.2022 ORCID: orcid.org/0000-0002-0144-3263

Cite this article as: Bülbül Başkan E. Determining disease severity. Turkderm-Turk Arch Dermatol Venereol 2022;56(Suppl 1):3-5

©Copyright 2022 by Turkish Society of Dermatology and Venereology Turkderm-Turkish Archives of Dermatology and Venereology published by Galenos Yayınevi.

widely today is the Dermatology Life Quality Index (DLQI)<sup>1,2</sup>. Looking at it from the patient's point of view, when the disease cannot be kept under control or becomes refractory, it is agreed to be severe. However, individualized disease severity and treatment goals can only be determined through a multidimensional and detailed assessment, not based on scales alone. Severity of psoriasis can be described as follows<sup>5</sup>:

### Mild plaque psoriasis

#### BSA $\leq 10$ / PASI $\leq 10$ / PGA $\leq 2$ and DLQI $\leq 10$

The treatment options in mild plaque psoriasis include topical treatments, and in resistant cases, phototherapy.

#### Moderate to severe plaque psoriasis

#### BSA ≤10 / PASI ≤10 / PGA >2 and DLQI >10

Despite a BSA and a PASI score less than 10, a DLQI score more than 10 reflects the negative effect of the disease on the patient and this situation generally arises in the presence of the following symptoms. Therefore, in the presence of these symptoms, the disease is classified as moderate<sup>5</sup>.

These symptoms are:

- Involvement of visible areas,
- Severe involvement of the hairy skin,
- Genital involvement,
- Involvement of the palms/soles
- Onycholysis or onychodystrophy in at least two nails,
- Presence of complaints such as itching, pain and burning sensation,
- Presence of recalcitrant plaques,
- Presence of arthritis.

The treatment options in moderate psoriasis include phototherapy, conventional systemic treatments and combination therapies.

The guideline group reached a positive consensus (at the highest level) in their delphi study about determining the disease severity based on collective assessment of PASI, DLQI, specific area involvement and resistance to prior treatments.

#### BSA >10 / PASI >10 / PGA >2 and DLQI >10

The treatment options in moderate to severe plaque psoriasis include conventional systemic treatments, combination therapies and biological therapies.

With a Delphi study, the International Psoriasis Council specified in 2019 a new category that can be used in treatment planning in clinical practices and patient recruitment for researches<sup>5</sup>. According to this consensus, patients with psoriasis will be assigned as topical or systemic treatment candidates and those who are systemic treatment candidates should meet at least one of the following three criteria:

1. BSA ≥10,

2. Involvement of special regions (the areas affecting quality of life considerably such as the face, palms, soles, hairy skin and nails),

3. Non-response to topical treatments.

The guideline group reached a positive consensus in their Delphi study about determining the disease severity based on collective assessment of PASI, DLQI, specific area involvement and resistance to prior treatments.

### **Description of treatment phases**

As in many chronic diseases, the treatment of psoriasis is also agreed to consist of two phases<sup>6</sup>. The first phase aims at complete or almost complete healing/elimination of lesions and the second phase at continuation and protection of the healing/elimination achieved.

#### Induction phase

This is the mean time required for the optimum clinical response to occur. The time it takes for the clinical effect to occur varies depending on the onset of action of the agents used in the treatment of psoriasis. For example, while efficacy can be observed within the first 10 weeks with some treatment agents such as cyclosporine, infliximab and adalimumab, this period is a little longer in a methotrexate therapy. The induction phase lasts between 10 and 16 weeks, and in some cases may be prolonged up to 24 weeks.

#### Maintenance phase

This is the time required to secure the continuation of the clinical efficacy achieved at the end of the induction phase. In this period, the patient is monitored at certain intervals with respect to the efficacy and safety of the drugs. Assessments with PASI and DLQI are conducted during these visits. The intervals are two-monthly for conventional systemic agents and three-monthly for biological drugs. Depending on the clinical progress, drug doses can be reduced, increased and combinations may be used in this phase. How long the maintenance phase should continue is not fully specified. When the treatment of psoriasis is discontinued, many patients may experience relapses, and sometimes even rebounds. The length of this phase may vary depending on the factors such as disease progression, personal factors, presence of comorbidities, and drug or patient safety.

#### Defining treatment goals

Defining goals in the treatment of psoriasis enables selection of appropriate treatments for an effective control of the disease and improvement of the quality of life. It also gives hints as to which practices should be followed if the treatment goal is not achieved within the expected period of time. Minimum goal in the treatment of psoriasis is to accomplish a 50% change in the PASI score, that is, to achieve PASI50. If PASI50 has not been achieved, the treatment should be modified no matter what the DLQI happens to be. What is acceptable in DLQI for a minimum significant recovery is at least 5-point reduction with treatment. Besides these scales, it is also recommended to consider other parameters including improvements in symptoms such as itching and pain, functioning, return to daily living and reduced treatment burden<sup>7,8</sup>. Treatment goals and acceptable periods of time to achieve them may vary depending on many factors such as the country's healthcare system and access to medication.

The guideline group reached a consensus in the Delphi study that the dermatological treatment goal to be achieved should be at least PASI75 and at least 75% recovery in BSA (at a very good level). A consensus (at a good level) was reached that the absolute DLQI score targeted in quality of life should be  $\leq 3$ .

A consensus (at a very good level) was reached that the time required for the treatment goal will change depending on the systemic treatment and should be accepted as 12 weeks on the average.



# Definition of treatment success at the end of the induction phase

A 75% or more decrease in the PASI score at the end of the induction phase, in other words, reaching at least PASI75 (or PGA  $\leq$ 2, DLQI  $\leq$ 5) is an acceptable success and the treatment will be continued.

After an ideal treatment, reaching at least PASI90 (or PGA  $\leq 1$ , DLQI  $\leq 1$ ) is expected (Table 1)<sup>9,10</sup>.

Tablo 1. Treatment goals in moderate psoriasis
1. Ideal treatment goal;
- PASI90
- PGA $\leq$ 1 or minimal disease (PGA $\leq$ 2 and PASI <5), which is under control with topical treatments
- DLQI ≤1
- Long-lasting remissions without loss of efficacy
- Stable progression of comorbidities
2. For a satisfactory response, at least one of the following should occur for longer than six months from the baseline;
- PASI75
- PASI <5
- PGA ≤1
- DLQI <5
3. Minimum efficacy criteria;
- PASI50
- PASI <50 and DLQI <5
Daudén et al. <sup>9</sup>
n 2017, American National Psoriasis Foundation declared achieving

In 2017, American National Psoriasis Foundation declared achieving BSA  $\leq$ 1 within the first three months as an ideal treatment goal and achieving BSA  $\leq$ 3 or PASI75 as an acceptable goal, thereby emphasizing BSA calculation as a simpler scale<sup>11</sup>.

# Definition of partial response at the end of the induction phase

If there is a decrease in the PASI score between 50% and 75% (or PASI  $\leq$ 10), DLQI is considered; if DLQI  $\leq$ 5 or there is a remission by at least 5 points, then the treatment is continued; if DLQI >5, then a modification in the treatment is recommended.

# Definition of failure at the end of the induction phase

A failure to achieve a 50% or more improvement in the PASI score, i.e. PASI50 (or PGA >2, PASI >10), at the end of the induction phase is interpreted as nonresponse without looking at the DLQI and a modification in the treatment is recommended. This is called a primary treatment failure and the drug dosage and frequency of administration or the drug itself may be changed, or an adjuvant may be added<sup>9</sup>.

## Definition of treatment success in the maintenance phase

If the success achieved in the induction phase i.e. PASI75 (or PGA  $\leq$ 2, PASI  $\leq$ 5) could be maintained, then the treatment will continue with a minimum effective dose.

## Definition of partial response in the maintenance phase

If PASI varies between 50 and 75% (or PASI  $\leq$ 10) during the maintenance treatment, then DLQI is considered. If DLQI is <5, the treatment continues, if DLQI  $\geq$ 5, the treatment will be modified.

## Definition of failure in the maintenance phase

If, during the maintenance treatment, the recovery rate declines below 50% or further down with respect to PASI at baseline (before induction), in other words, if it drops to PASI50 (or PGA >2, PASI >10), this indicates a treatment failure and the treatment needs to be modified<sup>8</sup>.

## Rebound

A 125% increase in the baseline PASI score within three months after the end of the treatment or a change in the morphology of psoriasis (erythrodermic or generalized pustular) is considered to be a rebound<sup>9</sup>.

### References

- Paul C, Gourraud PA, Bronsard V, et al.: Evidence-based recommendations to assess psoriasis severity: systematic literature review and expert opinion of a panel of dermatologists. J Eur Acad Dermatol Venerol 2010;24(Suppl 2):2-9.
- Langley RG, Ellis CN: Evaluating psoriasis with psoriasis area and severity index, Psoriasis Global Assessment, and Lattice System Physician's Global Assessment. J Am Acad Dermatol 2004;51:563-9.
- Nast A, Schmitt J: Physician Global Assessment (PGA) and Psoriasis Area and Severity Index (PASI): why do both? A systematic analysis of randomized controlled trials of biologic agents for moderate to severe plaque psoriasis. J Am Acad Dermatol 2013;68:1040-1.
- Radtke MA, Reich K, Spehr C, Augustin M: Treatment goals in psoriasis routine care. Arch Dermatol Res 2015;307:445-9.
- Strober B, Ryan C, van de Kerkhof P, et al.: Recategorization of psoriasis severity: Delphi consensus from the International Psoriasis Council. J Am Acad Dermatol 2020;82:177-22.
- Mrowietz U, Kragballe K, Reich K, et al.: Definition of treatment goals for moderate to severe psoriasis:a European consensus. Arch Dermatol Res 2011;303:1-10.
- Warren RB, Kleyn CE, Gulliver WP: Cumulative life course impairment in psoriasis: patient perception of disease-related impairment throughout the life course. Br J Dermatol 2011;164(Suppl1):1-14.
- Reich K, Mrowietz U: Treatment goals in psoriasis. J Dtsch Dermatol Ges 2007;5:566-74.
- Daudén E, Puig L, Ferrándiz C, Sánchez-Carazo JL, Hernanz-Hermosa JM; Spanish Psoriasis Group of the Spanish Academy of Dermatology and Venereology. Consensus document on the evaluation and treatment of moderate-to-severe psoriasis: Psoriasis Group of the Spanish Academy of Dermatology and Venereology. J Eur Acad Dermatol Venereol 2016;30(Suppl2):1-18.
- Grine L, de la Brassinne M, Ghislain PD, et al.: A Belgian consensus on the definition of a treat-to-target outcome set in psoriasis management. J Eur Acad Dermatol Venereol 2020;34:676-84.
- 11. Armstrong AW, Siegel MP, Bagel J, et al.: From the medical board of the national psoriasis foundation: treatment targets for plaque psoriasis. J Am Acad Dermatol 2017;76:290-8.

