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SPECIAL ARTICLE

Definition of treatment goals for moderate to severe psoriasis: a European consensus

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Abstract Patients with moderate to severe psoriasis are undertreated. To solve this persistent problem, the consensus programme was performed to define goals for treatment of plaque psoriasis with systemic therapy and to improve patient care. An expert consensus meeting and a collaborative Delphi procedure were carried out. Nineteen dermatologists from different European countries met for a face-to-face discussion and defined items through a four-round Delphi process. Severity of plaque psoriasis was graded into mild and moderate to severe disease. Mild disease was defined as body surface area (BSA) $\leq$10 and psoriasis area and severity index (PASI) $\leq$10 and dermatology life quality index (DLQI) $\leq$10 and moderate to severe psoriasis as (BSA $>$ 10 or PASI $>$ 10) and DLQI $>$ 10. Special clinical situations may change mild psoriasis to moderate to severe including involvement of visible areas or severe nail involvement. For systemic therapy of plaque psoriasis two treatment phases were defined: (1) induction phase as the treatment period until week 16; however, depending on the type of drug and dose regimen used, this phase may be extended until week 24 and (2) maintenance phase for all drugs was defined as the

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treatment period after the induction phase. For the definition of treatment goals in plaque psoriasis, the change of PASI from baseline until the time of evaluation (ΔPASI) and the absolute DLQI were used. After induction and during maintenance therapy, treatment can be continued if reduction in PASI is ≥75%. The treatment regimen should be modified if improvement of PASI is <50%. In a situation where the therapeutic response improved ≥50% but <75%, as assessed by PASI, therapy should be modified if the DLQI is >5 but can be continued if the DLQI is ≤5. This programme defines the severity of plaque psoriasis for the first time using a formal consensus of 19 European experts. In addition, treatment goals for moderate to severe disease were established. Implementation of treatment goals in the daily management of psoriasis will improve patient care and mitigate the problem of undertreatment. It is planned to evaluate the implementation of these treatment goals in a subsequent programme involving patients and physicians.

Keywords Psoriasis · Treatment goals · Severity · Patient care · Consensus

Introduction

Psoriasis is a chronic, immune-mediated inflammatory disorder affecting 2–3% of the Caucasian population in western countries [14]. Treatment of psoriasis can provide skin clearance but not a cure. In limited (mild) disease, the most commonly used therapy is topical with the addition of phototherapy in refractory cases. In moderate to severe psoriasis, phototherapy alone, combined with systemic therapy or systemic therapy alone is recommended. Recent guidelines present the level of evidence for the efficacy of the available therapies and give recommendation for their use in daily practice [12, 16, 23–25].

Despite the availability of a number of treatment options, surveys have shown that patients with psoriasis do not receive the optimal care that is necessary to clear their skin symptoms and to improve their health-related quality of life (HRQOL). Patients are frequently left on treatments for too long even though they may be ineffective. In general, dermatologists are reluctant to use systemic therapies [13].

The aim in defining treatment goals in psoriasis was to improve patient care with a major emphasis on HRQOL [3, 18]. In guidelines for treatment, drugs and therapeutic procedures are evaluated on the basis of the published clinical trial data. There is, however, no generally accepted consensus definition of either treatment success or failure. In patient care, there is a necessity to decide whether a drug or procedure is able to improve the disease at a given point of time. However, there is still a lack of a definition of a sufficient improvement in an individual patient's disease, but it likely depends on a combination of the drug's effectiveness, convenience and safety and patient-reported outcomes such as preference, satisfaction and improvement in HRQOL.

Whether a therapy is successful or not is directly linked to an action resulting from such a judgement which in effect means either continuation of therapy or modification of the therapeutic regimen.

Therefore, the definition of treatment goals is essential for maintaining a high standard of care. In a survey among dermatologists in Germany, psoriasis patients presented with a mean psoriasis area and severity index (PASI) of 12

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(moderate to severe disease) while under continuous care [1]. These data clearly indicate that psoriasis patients are both undertreated and underserved. A likely cause for this dilemma is the lack of treatment goals with an integrated demand for action.

It was the aim of this project to elaborate definitions for psoriasis severity and to define treatment goals on the basis of a European consensus. The programme included preparatory work and guidance by a steering committee, a consensus meeting with face-to-face discussion and establishment of the consensus by a Delphi procedure. Experts from 19 European countries participated in this programme. The work supplements existing guidelines such as the European Guideline on the treatment of psoriasis, the Dutch guideline, the German S3-guideline and the recent guidelines of the British Association of Dermatologists for the use of biologic therapies in psoriasis [12, 16, 23–25].

Common tools to score psoriasis include the determination of the area involved in relation to the whole body surface (body surface area, BSA), the psoriasis area and severity index (PASI) which evaluates lesions by their characteristics of erythema, induration and scaling as well as by the surface area affected and the physician's global assessment (PGA) aiming for an overall evaluation of lesion severity. In Europe, the PASI is a commonly used tool to grade psoriasis severity and is used in the majority of international clinical trials as primary or secondary endpoint. This score, despite some methodological limitations, is most useful in patients with moderate to severe psoriasis and has been shown to be a reliable instrument to evaluate treatment success or failure when patients are scored at baseline before treatment initiation and while on therapy [26]. The most commonly used outcome parameters to assess the impact of the disease on quality of life are the dermatology life quality index (DLQI) and the Skindex-29 [4]. The DLQI is a widely used scale which has been translated in all languages represented in the consensus programme and is available online free of charge for academic and office use [7].

There is no commonly accepted definition of limited (mild) versus moderate or severe psoriasis. In a consensus statement from the National Psoriasis Foundation [15], a group of North American experts divided plaque psoriasis into "candidates for localized therapy" with a BSA < 5 and "candidates for systemic and/or phototherapy" (BSA ≥ 5). In addition, the "rule of tens" defining current severe psoriasis (BSA > 10 or PASI > 10 or DLQI > 10) was suggested as a tool to grade clinical severity [8].

A clear definition of psoriasis severity has tremendous implications for a number of clinical decisions related to its management. These include therapeutic concepts and pharmacoeconomics.

The outcome of this consensus programme represents, to the best of our knowledge, the first definition of severity and of treatment goals in a chronic disorder based on a broad consensus established by a formal procedure. These consensus recommendations should lead to an improvement in the care of psoriasis patients. In order to evaluate if these aims are met, it is planned to evaluate the proposed treatment goals in a subsequent programme involving patients and dermatologists.

Methods

Structure of the European consensus programme

The goal of the programme was to produce European consensus on "Treatment goals for psoriasis". This is the opposite of a systematic collection of arguments and alternatives without the necessity to get consensus.

Two formal consensus methods were used: a consensus conference and the Delphi technique.

The Delphi technique can be characterized as a method for structuring a group communication process, thereby facilitating its ability to deal with a complex problem. To accomplish this structured communication there should be: some feedback of individual contributions of information and knowledge; assessment of the group's judgment or view; opportunities for individuals to revise views; a certain degree of anonymity for the individual responses and repetition [10].

Formal methods of consensus development are used because several people are less likely to arrive at a wrong decision than a single individual, and a selected group of individuals is more likely to lend some authority to the final decision. Furthermore, by providing a structured process, formal methods can eliminate negative aspects of group decision-making, and formal consensus methods meet the requirements of scientific methods. The advantage of the Delphi procedure is the formalized and recognized methodology, providing a structured group communication process. In our programme, we agreed to use the collaborative Delphi procedure in which the number of participants is manageable, and outputs/next steps are driven by the panel of participants.

All preparatory work including the definition of the structure and work flow was done by a steering committee (K.K., K.R., P.S. lead by U.M.) assisted by A.N. and J.F. C.E.M.G. served as a reviewer of the programme and of the final manuscript draft.

The consensus group consisted of dermatology experts on psoriasis management from 19 European countries. Each participant was chosen according to her/his recognition in the field or was nominated by their respective

national dermatology association. Personal participation in the consensus meeting held in Hamburg, Germany, February 12, 2009 was mandatory. Participants had to disclose their conflicts of interest and were able to vote for decisions made at the consensus meeting or later in the Delphi procedure. It was decided by the group that the Delphi procedure should not be anonymous. The members of the steering committee, programme reviewer and the assistants were excluded from voting in the Delphi rounds.

The programme was supported by an unrestricted educational grant from Abbott to the University Medical Center Schleswig-Holstein Campus, Kiel, Germany. The sponsor had no influence on the programme at any time. All financial transactions (e.g. reimbursement of travel costs, etc.) were processed through the finance department of the grant designee.

The consensus process started with presentations of the steering group at the consensus meeting. Comments and feedback were given on the initial steering group statements, and the rating of the importance of different steps to come to treatment goals was discussed. Agreements and disagreements were discussed, and the reasons and evidences behind these and alternative statements were developed. The full Delphi process consisted of four rounds. In the first Delphi round, structured questions were formulated on the issues to be addressed. An introduction was provided to explain how to fill out the questionnaire. Some background information was provided based on evidence and the knowledge of the steering group (from the second until the fourth round further development of questions was also based on participants' comments). In the first rounds for most questions two or more answers were possible; in subsequent rounds, fewer options were available. If agreement was achieved on certain items, this was mentioned in the text of the subsequent round questionnaire, and no more voting occurred on these.

Questionnaires sent out to the consensus group participants had to be completed and returned within 10 days of receipt (Fig. 2).

By definition, a vote of at least 17 out of 19 for acceptance of an item represented a strong consensus and was regarded as "agreement". The time between the rounds ranged between 5 and 10 weeks. The data management was descriptive.

Results

Definition of strength of agreement

It was agreed by the group that if 90% of the participants voted for an item this was defined as strong consensus or "agreement". By mathematical means, a vote of 17 out of 19 represents an 89.47% agreement. In Delphi round 3, there was a formal vote of all participants to regard a vote of 17 or more out of 19 as strong consensus or "agreement".

> "A vote of 17 or more out of 19 voters is regarded as a strong consensus and equals 90% ('agreement')".
> (Delphi-result: vote 19/19 = agreement, round 3)

Severity of plaque psoriasis

The first part of the programme was to define the severity of psoriasis. Based on clinical considerations and the later generation of treatment goals, it was decided to use the established scores BSA and PASI for the grading of psoriasis symptoms (scaling, erythema and induration/infiltration) and extent of lesions. It was further decided to include an instrument to assess HRQOL in order to employ an independent measure of patient-reported psoriasis severity. Although there were country-specific differences in the preferred validated instrument, it was consented by the group to use the DLQI for the definitions.

Definition of plaque psoriasis severity

> "Psoriasis severity is defined in two main categories: mild versus moderate-to-severe."
> (Delphi-result: vote 18/19 = agreement, round 1)

There was intense discussion among all experts on how to define "mild" and "moderate to severe" plaque psoriasis by using BSA, PASI and DLQI. There was agreement, however, that a single unifying definition could not include all clinical situations which may be present in a psoriasis patient.

Definition of mild plaque psoriasis

BSA $\leq$ 10 and PASI $\leq$ 10 and DLQI $\leq$ 10.

In accordance with existing guidelines, it is recommended to treat mild psoriasis with topical agents.

> "If BSA $\leq$ 10 and PASI $\leq$ 10 indicates mild disease but DLQI $>$ 10 indicates significant impact on quality of life psoriasis can be considered moderate to severe and systemic therapy may be initiated when the patient's disease cannot be controlled by topical treatment."
> (Delphi-result: vote 17/19 = agreement, round 4)

Mild plaque psoriasis can usually be controlled by topical therapy. In refractory cases, the addition of phototherapy should be considered. However, patients with mild psoriasis, as indicated by the somatic scores, BSA and

PASI, may present with disease manifestations not adequately controlled by topical therapy alone which, in addition, may lead to a significantly impaired quality of life. These manifestations can include the following:

- involvement of visible areas,
- involvement of major parts of the scalp,
- involvement of genitals,
- involvement of palms and/or soles,
- onycholysis or onychodystrophy of at least two fingernails,
- pruritus leading to scratching and
- presence of single recalcitrant plaques.

The Consensus Group recognized that the presence of disease manifestations listed above may alter the classification of mild disease (PASI $\leq$ 10, BSA $\leq$ 10, DLQI $\leq$ 10) to moderate to severe disease that warrants phototherapy, systemic treatment, combination therapy or special procedures including Excimer-laser or occlusive topical treatment in individual cases. However, there was an agreement not to include these items in a general definition of plaque psoriasis severity.

Definition of "moderate to severe" plaque psoriasis

(BSA $>$ 10 or PASI $>$ 10) and DLQI $>$ 10

In accordance with existing guidelines, it is recommended to treat moderate to severe psoriasis with phototherapy or systemic treatments.

> "If BSA $>$ 10 or PASI $>$ 10 indicates moderate to severe disease but DLQI $\leq$ 10 indicates no significant impact on quality of life psoriasis can be considered mild disease."
> (Delphi-result: vote 17/19 = agreement, round 2)

Treatment phases for systemic therapy of plaque psoriasis

Definition of induction and maintenance phase for systemic treatment of psoriasis

The different drugs licensed for topical or systemic treatment of psoriasis have different profiles related to onset of action and overall efficacy. For example, with the tumour necrosis factor α-antagonist infliximab, there is a fast onset of action and an almost maximum therapeutic response by week 10 of treatment [17]. On the other hand, methotrexate or fumarates have a slower onset of action, and the maximum therapeutic response may only be achieved after several months of treatment [19, 21]. It was found necessary to provide a broader definition of induction and maintenance therapy, taking into account the different profiles of the drugs used.

Definition of induction phase

> "Induction phase is generally defined as the treatment period until week 16; however, depending on the type of drug and dose regimen used, induction phase can be extended until week 24 according to the decision of the treating dermatologist."
> (Delphi-result: vote 17/19 = agreement, round 2)

Definition of maintenance phase

> "Maintenance phase is defined for all drugs as the treatment period after the induction phase; therapeutic success should be assessed in intervals according to recommendations in the available guidelines."
> (Delphi-result: vote 19/19 = agreement, round 1)

Treatment goals

The ultimate goal of any psoriasis treatment is to achieve complete clearance of skin symptoms. However, the current definition of treatment goals has to be based upon the results achievable with available treatments as indicated by the results of randomized controlled trials and the outcomes observed in clinical practice.

In order to provide optimal therapy to patients, it should be ensured that a therapy which was unable to induce a certain degree of improvement is replaced by a therapeutic alternative after a given period of time. Therefore, the definition of treatment goals needs a minimal degree of improvement (principle of the lowest hurdle) and the drug-specific evaluation time points. The assessment should first be made at the end of induction therapy (i.e. the time point at which the optimal clinical response of a given drug can be expected) and later during maintenance treatment in regular intervals which may match with monitoring recommendations in the respective guidelines.

There are three scenarios in which treatment goals need to be defined and in which advice is needed as to which action has to be taken related to the outcome of the judgement.

The first is when treatment is successful, and the second when treatment is unsuccessful. The third scenario represents an in-between response with a certain degree of improvement which can neither be classified as success nor failure.

If the treatment goal is not met, it is recommended to modify therapy. Such modification may be adjustment of

dose, addition of another treatment (combination therapy) or switching to another therapy.

Definition of treatment success after induction phase

> "If at the end of the induction phase a reduction in PASI of ≥75% (ΔPASI ≥ 75%) as compared to disease severity at the time of treatment initiation has been achieved, it is recommended to continue the treatment regimen."
> (Delphi-result: vote 19/19 = agreement, round 3)

Definition of treatment failure after induction phase

> "If at the end of the induction phase an improvement of PASI of ≥50% (ΔPASI ≥ 50%) as compared to disease severity at the time of treatment initiation has not been achieved, it is recommended to modify the treatment regimen."
> (Delphi-result: vote 19/19 = agreement, round 3)

In patients, where treatment response as assessed by PASI was ≥50% but <75%, the impact of the remaining disease on quality of life using the DLQI will be used as a decision-making tool to either continue or to modify the treatment regimen.

Definition of intermediate response to treatment after induction phase

> "If at the end of the induction phase an improvement of PASI of ≥50% but <75% (ΔPASI ≥ 50% <75%) as compared to disease severity at the time of treatment initiation has been achieved, but DLQI ≤ 5 has not been achieved, it is recommended to modify the treatment regimen."
> "If at the end of the induction phase a reduction in PASI of ≥50% but <75% (ΔPASI ≥ 50% <75%) as compared to disease severity at the time of treatment initiation and DLQI ≤ 5 has been achieved, is recommended to continue with the treatment regimen."
> (Delphi-result: vote 19/19 = agreement, round 3)

During the maintenance phase, treatment response should be monitored regularly and compared to the situation at baseline before treatment initiation. For most systemic drugs, according to published guidelines, safety monitoring is recommended at bimonthly intervals. During these visits, treatment outcomes should be assessed by PASI and DLQI. In relation to this assessment, the decision as to whether to continue or to modify the therapeutic regimen should be based (Fig. 2).

Definition of treatment success during maintenance phase

> "If during maintenance therapy an improvement of PASI of ≥75% (ΔPASI ≥ 75%) as compared to disease severity at the time of treatment initiation has been achieved, it is recommended to continue with the treatment regimen."
> (Delphi-result: vote 17/19 = agreement, round 4)

Definition of treatment failure during maintenance treatment

> "If during maintenance therapy an improvement of PASI of ≥50% (ΔPASI ≥ 50%) as compared to disease severity at the time of treatment initiation has not been achieved, it is recommended to modify the treatment regimen."
> (Delphi-result: vote 17/19 = agreement, round 4)

Definition of intermediate response to treatment during maintenance phase

> "If during maintenance therapy an improvement of PASI of ≥50% but of less than 75% (ΔPASI ≥ 50% <75%) as compared to disease severity at the time of treatment initiation can be maintained, but DLQI ≤ 5 has not been achieved, it is recommended to modify the treatment regimen."
> "If during maintenance therapy an improvement of PASI of equal or more than 50% but of less than 75% (ΔPASI ≥ 50% <75%) as compared to disease severity at the time of treatment initiation can be maintained and DLQI ≤ 5 has been achieved, it is recommended to continue with the treatment regimen."
> (Delphi-result: vote 17/19 = agreement, round 4)

Discussion

The management of chronic disease is dependent upon clear ideas about the goals of treatment. This is due to the considerable heterogeneity of the clinical expression of diseases such as psoriasis and the varying response to any therapy. In all clinical trials for the treatment of plaque psoriasis published to date, there is no single drug or regimen to which all patients respond. Variability in patient response to any given drug is still poorly understood, but is in part dictated by pharmacogenetics. Even when a treatment response is seen, the degree of response/improvement is variable among patients irrespective of dose and time of

treatment. The situation is further complicated by the temporal nature of drug response in that patients at one time can show improvement to an administered drug, but show only partial or even no response to the same drug given at a later time-point. Biomarkers or predictors of clinical response are not currently available for plaque psoriasis.

Well-defined treatment goals may be helpful to guide physicians in their care of patients with psoriasis, thereby obviating poor outcomes.

In a recent screening of publications in the rheumatology literature concerning definitions of success or failure of treatment particularly for rheumatoid arthritis, there was no unifying consensus of a practical definition of either treatment failure or clinical remission. The definitions used ranged from complete absence of any clinical disease to computer-generated numeric scales. It was concluded that the variability in clinical definitions of either treatment failure or remission seems to have been attributed mainly to the time at which assessments were made, making it difficult to determine what these actually mean in clinical practice [2]. A survey of experts in the management of rheumatoid arthritis revealed that they were well informed about recent concepts, but only two-thirds of them specified remission as a major goal of treatment. The experts attempted to reach treatment goals within 12–14 weeks of initiation of treatment and were willing to modify therapy otherwise. There was no consensus on how to assess outcomes best as disease activity assessment by composite scores was done by a majority of experts; however, one-third of them preferentially relied upon their personal clinical judgement [22]. This dilemma led to some initial attempts to define criteria for treatment success or failure, but no consensus has been published to date [5].

Despite the availability of a great number of treatment options for psoriasis, surveys have shown that psoriasis patients do not receive the optimal care that is necessary to clear their skin symptoms and to improve their quality of life [1, 6, 13]. A retrospective, patient-record analysis by Gillard and Finlay [9] based on data from a primary-care medical record database for the years 2002–2003 in the UK demonstrated that only 245 (4%) of 6,120 patients with psoriasis received either phototherapy or systemic therapy. The large majority of patients (93.6%) received topical treatment only [9]. In 2007, in private dermatological practices in Germany, systemic treatments were prescribed in only 31% of visits made by patients suffering from moderate to severe psoriasis [1]. Patient-oriented studies of members of psoriasis patient support associations have shown low patient satisfaction with current treatment regimens and high rates of non-compliance [6, 20, 27].

Thus, a definition of treatment goals was recently discussed for plaque psoriasis, and a first attempt was made to define a minimum degree of efficacy which should be achieved by topical, phototherapy or systemic therapy evaluated at different time points [18]. The aim of this consensus approach was to identify and discuss the needs for patients with plaque psoriasis related to treatment outcomes and to elaborate strategies which can be applied in general without country-specific restrictions. To achieve this goal, dermatologist from 19 European countries with a particular interest in psoriasis met in a consensus conference for a face-to-face discussion of a proposal produced by a steering committee. The outcome of the discussion was taken as basis of a following consensus step for which the well-established Delphi procedure was employed. In the Delphi rounds, questionnaires were answered by the group of experts, and definitions refined for the next round according to voting and comments. After a completion of four rounds, the results were regarded valid for publication as a consensus (Fig. 1).

It was necessary to first define severity of psoriasis before treatment goals were set.

There was agreement to separate plaque psoriasis into two groups related to disease severity: mild and moderate to severe. A further refinement was achieved by using the internationally accepted parameters BSA and PASI. As for another widely used score, PGA, a major drawback is the lack of a common definition, and therefore, this was not found useful. Emphasis was on strength of an instrument to assess quality of life in order to integrate an independent parameter to assess psoriasis severity. Although a number of different scales are available such as Skindex-29, Short-Form 36 and others used in some countries as a primary tool to measure HRQOL, it was decided to use the DLQI as in the majority of countries, which is employed most often [4]. The DLQI has been used worldwide in numerous clinical trials and investigations on life quality and burden of disease. In addition, it is available in all languages spoken in the countries represented by the group and is accessible through the internet (http://www.dermatology.org.uk/quality/quality-dlqi.html) [7]. According to published data, there is a definition of the different scores of the DLQI and their impact on patients' life which allows a reliable grading of quality of life [11]. By using this definition, a DLQI < 5 indicates only mild impact on an individual patients' quality of life.

The definition of mild psoriasis follows the rule of tens as proposed by Finlay and co-workers [8]. Refining this rule, the definition agreed upon by the Consensus Group is BSA ≤ 10 and PASI ≤ 10 and DLQI ≤ 10. Mild psoriasis can normally be controlled by topical therapy. However, certain clinical meaningful aspects of psoriasis can result in a DLQI > 10 while severity of skin symptoms and body surface involvement is still mild. Such circumstances may lead to a modification of treatment, and psoriasis can be considered moderate to severe.

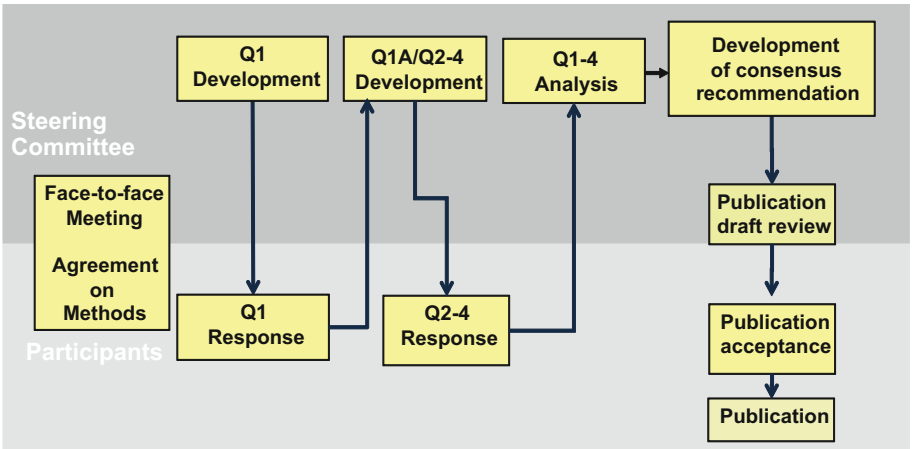

Fig. 1 Flowchart of the collaborative Delphi procedure employed in this European consensus programme

Moderate to severe psoriasis is defined as (BSA > 10 or PASI > 10) and DLQI of >10. This severity of psoriasis can no longer be controlled by topical therapies. In patients, where body involvement and plaque characteristics indicate moderate to severe disease but a DLQI is <10 indicating only limited impact on quality of life, an individual therapeutic approach should be taken by the treating dermatologist.

For the definition of treatment goals, it was necessary as a first step to define time points at which assessment of disease severity should be made. Two main phases of treatment were set: induction and maintenance. Induction phase characterizes the time between the start of therapy and the induction of remission. In the discussion, it became apparent that there is a great heterogeneity in the ability of different drugs to induce remission and to reach a plateau of efficacy. It was proposed, therefore, to define induction phase until week 16 but to allow extension until week 24 when drugs or regimens with a known slow onset of action are used. Maintenance phase was defined as the treatment phase after induction phase. As this period can vary from a few weeks to several years dependent on individual patient need, regular clinic visits to monitor safety and the achievement of treatment goals should be scheduled according to the recommendations given in the guidelines [12, 16]. In clinical practice, this time frame for most systemic drugs is 2 months.

The definition of treatment goals is meant to secure an efficacious treatment with regard to the control of clinical symptoms and to substantiate improvement in quality of life. Another most important consequence when defining treatment goals is the need for corrective action in the case of the goal not being achieved. This is related to the question of a meaningful clinical outcome and a minimum requirement which must be fulfilled. The Consensus Group elected to use the PASI together with the DLQI to define treatment goals. It was further decided to generate separate treatment goals for induction and maintenance phases. Interestingly, during the Delphi process, it became clear that the definitions for induction and maintenance phases were similar.

The minimum requirement for the efficacy of any therapy was defined to be an at least 50% reduction in the baseline PASI, irrespective of the DLQI. If this is not met, the treatment should be modified. Such modification could be a dose adjustment, addition of another therapy (combination treatment) or transition to another drug or modality. When PASI is reduced by at least 75%, the treatment regimen can be continued. If the therapeutic effect is a reduction in PASI of at least 50% but less than 75%, it is recommended to decide whether to modify the therapeutic regimen according to DLQI. There was a decision of the group of experts to set a DLQI ≤ 5 or >5 as a criterion when to modify treatment (Fig. 2) based on a categorization study of the DLQI [11].

It is important to state that division of psoriasis into either mild or moderate to severe disease before initiation of treatment will not be changed afterwards by the response to the treatment chosen. It has been clearly shown that in the majority of patients, stopping treatment will eventually result in recurrence or relapse. In a minority of patients, stopping treatment may result in deterioration of psoriasis beyond the baseline severity known as rebound. The current status is that therapies used for psoriasis can clear or improve skin symptoms, but are unable to either cure the disease or induce long-lasting, disease-free remission. Even after achievement of complete skin clearance, the disease activity may still be high resulting in rapid deterioration when treatment is terminated or the dose of medication decreased.

Our consensus programme was able to define a number of important items related to psoriasis therapy. Experts from 19 European countries agreed on a: (1) grading of plaque psoriasis into either mild or moderate to severe, (2) definition of induction and maintenance phases and (3) most importantly, treatment goals for both phases. This is a unique approach which to date has been unexplored for

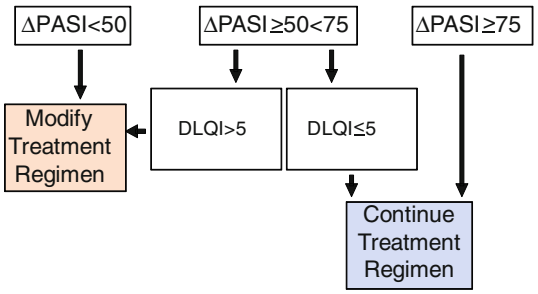

Fig. 2 Definition of successful and non-successful therapy after induction and during maintenance treatment of moderate to severe plaque psoriasis. In the eventuality that a treatment regimen should be modified, the following measures should be employed: dose adjustment, addition of another therapy (combination treatment) or transition to another drug or modality

either plaque psoriasis or for other chronic inflammatory diseases. The main objective of the consensus programme was to improve patient care and help dermatologists regularly assess outcomes achieved with established therapies. It will be of major importance to familiarize the dermatological community with such an approach, so it can be utilized for daily practice.

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