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Comparing treatment goals for psoriasis with treatment decisions in daily practice: results from a prospective cohort of patients with psoriasis treated with biologics: BioCAPTURE*

J. Zweegers,[1] J.M.P.A. van den Reek,[1] P.C.M. van de Kerkhof,[1] M.E. Otero,[1] P.M. Ossenkoppele,[2] M.D. Njoo,[2] J.M. Mommers,[3] M.I.A. Koetsier,[4] W.P. Arnold,[5] B.A.M. Sybrandy-Fleuren,[6] A.L.A. Kuijpers,[7] M.P.M. Andriessen,[8] W. Kievit[9] and E.M.G.J. de Jong[1]

[1]Department of Dermatology and [9]Department of Epidemiology, Biostatistics and Health Technology Assessment, Radboud University Medical Center, René Descartesdreef 1, Nijmegen 6525 GL, the Netherlands
[2]Department of Dermatology, Ziekenhuisgroep Twente, Almelo/Hengelo, the Netherlands
[3]Department of Dermatology, St Anna Ziekenhuis, Geldrop, the Netherlands
[4]Department of Dermatology, Gelre Ziekenhuizen, Apeldoorn, the Netherlands
[5]Department of Dermatology, Ziekenhuis Gelderse Vallei, Ede, the Netherlands
[6]Department of Dermatology, Slingeland Ziekenhuis, Doetinchem, the Netherlands
[7]Department of Dermatoogy, Maxima Medisch Centrum, Eindhoven/Veldhoven, the Netherlands
[8]Department of Dermatology, Jeroen Bosch Ziekenhuis, Den Bosch, the Netherlands

Summary

Background Treatment goals have been developed to optimize daily clinical practice psoriasis care, but have not yet been studied in real life.
Objectives To investigate to what extent treatment decisions made by dermatologists in daily clinical practice for patients with psoriasis on biologics are already in accordance with treatment goals without the active application of the treatment goals algorithm.
Methods Data were extracted from a prospective daily practice cohort of patients with psoriasis on biologics. Analysis was done on effectiveness (Psoriasis Area and Severity Index score) and quality of life (Dermatology Life Quality Index questionnaire). Treatment decisions such as dosage adjustments, combination treatments, or switching therapy were compared with the treatment goals algorithm.
Results In 64% (253 of 395) of visits, physicians followed the treatment goals algorithm. There were 162 (41%) visits in which there should have been a treatment modification according to treatment goals (group Modify) and a modification was indeed made in 59 of these 162 visits (36%). In 233 (59%) visits no treatment modification was necessary (group Continue) and therapy was indeed not modified in 194 of 233 visits (83%).
Conclusions Physicians acted in accordance with treatment goals in the majority of patient visits. In the patient group not achieving these goals, physicians should have modified therapy according to treatment goals but continued the same therapeutic regimen in the majority of visits. Optimizing therapy and defining barriers in the latter group might increase treatment results in daily practice psoriasis care.

What's already known about this topic?

- A European consensus on treatment goals was established in 2011 to guide physicians in the treatment of psoriasis.

Correspondence
Jeffrey Zweegers.
E-mail: Jeffrey.Zweegers@radboudumc.nl

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- These treatment goals have been evaluated for adalimumab therapy using data from three randomized clinical trials.

What does this study add?

- Treatment decisions made by dermatologists for patients with psoriasis on biologics in daily clinical practice are already in accordance with the treatment goals from before application of the European consensus.
- This study provides a starting point from which to evaluate the influence of the actual implementation of treatment goals in daily practice.

Psoriasis is a chronic skin disease with great impact on the quality of life (QoL) of patients.[1,2] Moderate-to-severe psoriasis is usually treated with systemic and biologic therapies, although undertreatment does occur.[3–5] In order to guide physicians with treatment decisions in daily practice, a European consensus on treatment goals was published in 2011.[3,6] These treatment goals advise to continue treatment when baseline Psoriasis Area and Severity Index (PASI) score has improved by at least 75% (PASI 75; treatment success) or when a Dermatology Life Quality Index (DLQI) score of ≤ 5 is reached in patients with a PASI score improvement of between 50% and 75% (PASI 50–75; intermediate response). In contrast, treatment should be adjusted when PASI 50 is not reached (treatment failure) or when treatment response is intermediate with a DLQI score of > 5.[3] Modification strategies include increasing dosage of current therapy or reducing treatment intervals, adding topical or systemic therapy, or changing the drug.[6] Treatment goals are shown in Figure 1. Recently, treatment goals have been evaluated for adalimumab therapy using data from three randomized clinical trials (CHAMPION, REVEAL and BELIEVE).[7] However, treatment goals have been formulated for use in daily clinical practice and it is known that the daily practice patient differs substantially from the clinical trial patient.[8] In addition, daily practice patients are being treated according to the opinion of their physician and therefore treatment decisions may vary considerably.

The main objective of this study was to investigate to what extent treatment decisions made in clinical practice are already in accordance with the treatment goals without the active application of the treatment goals algorithm. This may allow us to identify the gap between daily practice and the future situation after optimal implementation of treatment goals.

Methods

BioCAPTURE registry

For this study, data were used from the prospective registry BioCAPTURE that contains data from all patients with psoriasis treated with biologics from 2005 until now who gave informed consent. One academic and eight nonacademic centres participate in data collection. The BioCAPTURE registry was approved by the medical ethics committee of the Radboud University Medical Center.

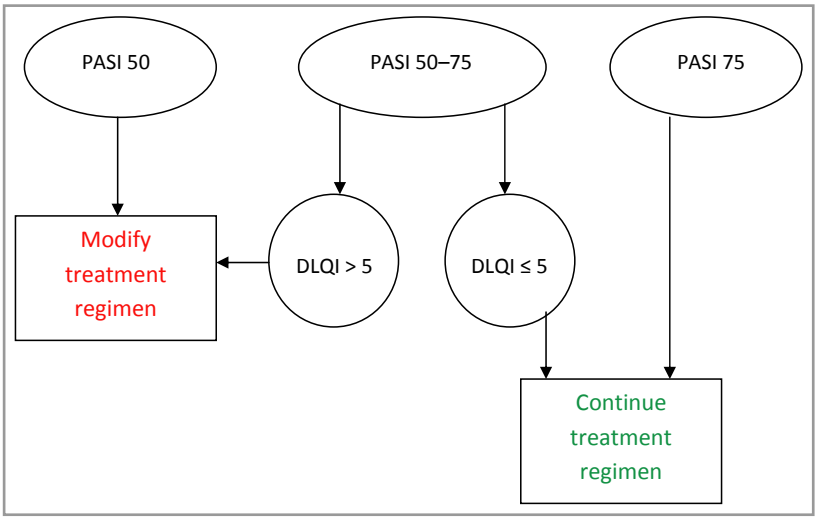

Fig 1. Treatment goals in psoriasis. Adapted from Mrowietz *et al.*[3]

Patients

Patients treated between 1 March 2010 and 31 December 2012 were included in the present analysis. Patient characteristics were collected including sex, family history of psoriasis, psoriatic arthritis, mean baseline PASI score at the start of therapy, body mass index, age at onset of disease and age at start of the biologic. Patients were treated with biologics (etanercept, adalimumab, infliximab and ustekinumab) according to European and Dutch guidelines on psoriasis treatment. Patients were allowed to have multiple treatment episodes (TEs) that were defined as continuous treatment periods with one of the aforementioned biologics. A treatment interruption of 90 days during treatment with the same drug was allowed. During treatment, patient visits were scheduled every 3 months.

Assessments

To measure psoriasis severity, PASI scores were calculated at every visit and registered in the database.[9] Physicians were trained by an experienced research nurse to assess PASI scores. Scores were regularly double-checked by this nurse. From March 2010, DLQI measures were conducted every 3 months during the first year and every year thereafter in patients starting on biologics or switching to new biologics. The DLQI is a validated questionnaire measuring QoL in patients with dermatological conditions and has been translated into different languages.[10,11] Lower DLQI scores indicate better QoL. Data on biologic treatment, conventional systemic and intensive topical (i.e. dithranol) treatment during the study period were recorded, as well as dosages of antipsoriatic medication. PASI scores, DLQI data and information on treatment decisions were extracted from the database for patient visits at baseline (i.e. start of medication) and at months 3, 6, 9 and 12. During patient visits, PASI scores were visible for treating physicians whereas PASI percentages compared with baseline and DLQI scores were not. Therefore, patients were treated without the knowledge of whether patients reached treatment goal criteria for treatment modification or continuation of treatment without modification (Fig. 1).

Data analysis

PASI scores were compared with baseline (month 0) in order to calculate PASI percentages for included visits. Hereafter, patient visits were grouped into three PASI percentage groups according to treatment goals in order to calculate the number of visits with treatment success (i.e. PASI 75): (1) PASI 50, (2) PASI 50–75 and (3) PASI 75. In accordance with the treatment goals, the DLQI was calculated for patient visits in the intermediate response group (PASI 50–75) to discriminate between high QoL (DLQI $\leq$ 5) and low QoL (DLQI $>$ 5). If no DLQI score was available for a visit in the intermediate group, this visit was excluded from further analyses. Subsequently, information on treatment decisions for all included visits was extracted from the database at months 3, 6, 9 and 12 with a range of 2 weeks prior to and 2 weeks after the defined month. After that, patient visits were grouped into (a) group Modify, in which treatment modification is recommended according to treatment goals and (b) group Continue, in which the treatment regimen may be continued and no treatment modifications are necessary according to treatment goals. In these two groups, it was recorded how often modifications were indeed carried out, and how often treatment was not changed.

Treatment modifications made by physicians were described and grouped as follows: (1) increasing dose (or reducing dose intervals) of the biologic, (2) increasing dose of conventional systemic drug, (3) increasing dose of both biologic and conventional systemic drug, (4) decreasing dose of biologic, (5) decreasing dose of conventional systemic drug, (6) decreasing dose of both biologic and conventional systemic drug, (7) adding conventional systemic therapy to a biologic, (8) adding intensive topical therapy (i.e. dithranol), (9) switching of therapy, and (10) other modifications.

As baseline PASI scores might influence the ability to reach PASI 75, the median baseline PASI scores were calculated in groups Modify and Continue, and compared. To assess the difference in QoL between groups Modify and Continue, median DLQI scores were calculated and compared. For group Modify, a subanalysis of DLQI was performed for patient visits in which a modification in treatment was indeed made compared with those visits in which the same therapeutic regimen was continued.

Statistics

Descriptive statistics were used and expressed as percentages, means $\pm$ SD or median (range). In the case of repeated measures within patients only descriptive statistics were used. The Mann–Whitney U-test was used to compare baseline PASI scores between groups Modify and Continue. The P-value was set at 0·05. IBM SPSS Statistics 20 (IBM, Armonk, NY, U.S.A.) was used for analyses.

Results

Patients

A total of 161 patients were identified from our cohort with 192 TEs (Fig. 2). TEs with only one PASI score at baseline or without a baseline PASI score were excluded (n = 28). This resulted in 164 TEs from 139 patients and 454 visits for which a PASI percentage could be calculated. Patient characteristics are shown in Table 1. Of the 164 TEs, in 72 (44%) TEs adalimumab therapy was prescribed, in 54 (33%) TEs etanercept, in 33 (20%) TEs ustekinumab and in five (3%) TEs infliximab therapy was prescribed.

Assessments

There was a PASI 50 response in 30% (134 of 454), a PASI 50–75 response in 30% (138 of 454) and a PASI 75 response

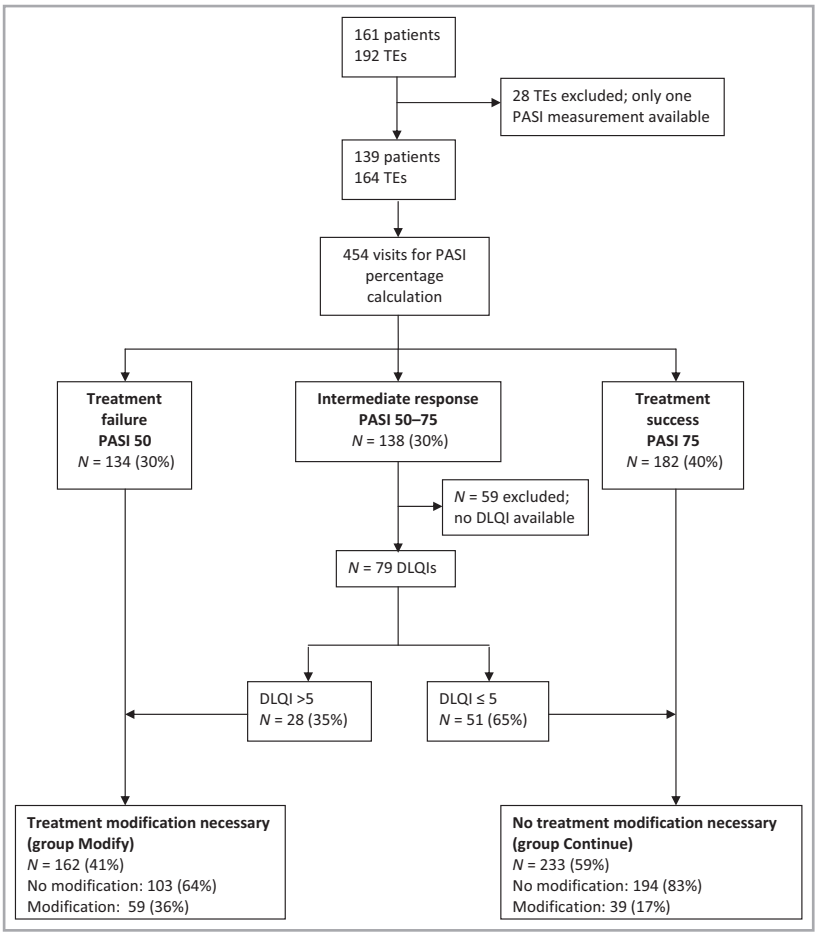

Fig 2. Flowchart of PASI responses, DLQI scores and treatment modification in the prospective daily practice cohort BioCAPTURE. The treatment goals flowchart using daily practice data from patients with psoriasis on biologics in the BioCAPTURE cohort. TEs, treatment episodes; PASI, Psoriasis Area and Severity Index; DLQI, Dermatology Life Quality Index.

(treatment success) in 40% (182 of 454) of visits (Fig. 2). After excluding 59 visits due to missing DLQIs, 395 visits were left for analyses. In 41% of visits (162 of 395) treatment should have been modified (group Modify) and in 59% (233 of 395) therapy did not have to be modified (group Continue) according to treatment goals. The median baseline PASI score was significantly lower in group Modify [10·5 (0·6–38·4)] than in group Continue [12·2 (3·8–42·1), P = 0·004].

DLQI scores for included visits were grouped based on PASI percentage achieved (Fig. 3). In groups PASI 50 and PASI 50–75 with a DLQI score, 41% and 35% of visits, respectively, showed a DLQI score of > 5, representing low QoL according to treatment goals. However, when PASI 75 was reached, 19% of visits showed a DLQI > 5. In visits with a PASI 75 response, 50% of DLQI scores were 0, indicating optimal QoL compared with 7% in visits with a PASI 50 response.

Median DLQI at visits for those in group Modify was compared with median DLQI of group Continue patients on their visits. Scores were 6·00 (0–30) and 1·00 (0–16), respectively, indicating a higher QoL in group Continue.

Within group Modify, two subgroups were present: one with treatment modification and one without modification (Fig. 2). Median DLQI at visits was compared between these subgroups: 7·00 (0–16) vs. 6·00 (0–30) for modified and not modified, respectively.

Treatment decisions

The treatment goals algorithm was followed by physicians in 64% (253 of 395) of visits (Fig. 2); in group Modify, therapy was indeed modified in 59 of 162 visits, and in group Continue therapy was continued without modification in 194 of 233 visits. Table 2 shows the numbers of treatment decisions for groups Modify and Continue. In both groups,

Table 1 Patient characteristics (total n = 139)

Patient characteristics	N = 139
Male sex, n (%); N = 139	88 (63·3)
Positive family history of psoriasis, n (%); N = 133	85 (61·2)
Psoriatic arthritis, n (%); N = 123	44 (31·7)
BMI, median (range); N = 101	28·0 (17·7–53·2)
Baseline PASI score, median (range); N = 139	11·2 (2·0–42·1)
Age at onset of psoriasis (years), mean ± SD; N = 136	24·8 ± 13·0
Age at start of biologic therapy (years), mean ± SD; N = 139	47·4 ± 13·0

BMI, body mass index; PASI, Psoriasis Area and Severity Index.

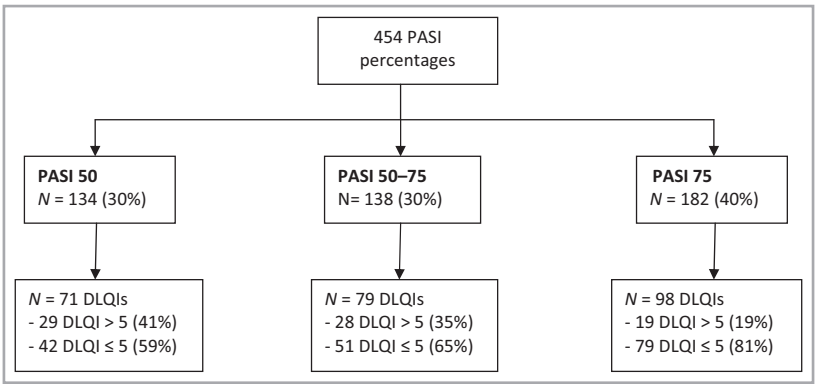

Fig 3. DLQI scores for different PASI percentage groups. DLQI scores from psoriasis patients in the BioCAPTURE cohort. DLQI, Dermatology Life Quality Index; PASI, Psoriasis Area and Severity Index.

there were no treatment modifications due to a serious adverse event.

Modification necessary according to treatment goals (group Modify)

In group Modify, in 36% (59 of 162) of visits therapy was indeed modified and in 64% (103 of 162) of visits therapy was not modified. There were 61 modifications (Table 2). Most often (46%; 28 of 61) a dose increase of biologic, conventional systemic or both was carried out. Of these, a dose increase of the biologic was the most frequently applied strategy. In 18% (11 of 61) of modifications there was a switch to another biologic. In 13% (8 of 61) of modifications there was an interruption or restart of biologic or conventional systemic therapy. In 11% of modifications (7 of 61) it was decided to decrease the dose of biologic or conventional systemic therapy, despite a PASI 50 response or a PASI 50–75 response with a DLQI > 5. One dose decrease included etanercept from 2×50 mg per week to 1×50 mg per week according to label at month 3. Conventional systemic therapy was stopped twice; methotrexate was stopped due to desire for pregnancy and ciclosporin was stopped because it was prescribed only as bridging therapy. By month 3, 41% (25 of 61) of modifications had already been made. At this time point, a switch to another biologic was the most frequently chosen treatment strategy, followed by a dose increase of biological therapy.

No modification necessary according to treatment goals (group Continue)

In group Continue, in 83% (194 of 233) of visits the same therapeutic regimen was indeed continued. In 30 of 194 (15%) visits, the biologic dose could have been decreased by physicians because treatment goals were reached but a high dose was continued.

In 17% (39 of 233) of visits there were 40 modifications (Table 2). Most often (65%; 26 of 40) the dose of biologic or conventional systemic was decreased. Of these, dose decrease of biologic was the most frequent. Twelve modifications included the decrease of etanercept dose from 2×50 mg per week to 1×50 or 2×25 mg per week according to label at month 3. In two modifications (5%), low-dose methotrexate was added as combination therapy. The dose of biologic was increased in 18% of modifications (7 of 40). As shown in Table 2, there was no switch of therapy in group Continue. Forty-three per cent of modifications (17 of 40) were made in month 3. The most frequently applied modification in this subgroup was a dose decrease of the biologic.

Discussion

In this prospective daily practice cohort of patients with psoriasis treated with biologics, in the majority (64%) of visits physicians followed the treatment goals algorithm intuitively. In 59% of visits, treatment goals were reached. In a large percentage of visits (64%) in which patients needed adjustment of therapy according to the treatment goals, no treatment modifications were made by physicians.

One study recently assessed adalimumab efficacy in three phase III clinical trials using psoriasis treatment goals as the evaluation method.[7] This study showed that in the CHAMPION, REVEAL and BELIEVE studies at week 16, treatment success was achieved by 79·3%, 72·1% and 68·2%, respectively. Moreover, treatment goals for continuing therapy without modification were reached by > 70% of patients. In our study, the percentages were lower: 40% of visits achieving treatment success and 59% of visits reaching treatment goals. However, in the present analysis we used data from all biologics available instead of only adalimumab, and in a daily practice setting in contrast to a randomized controlled trial. In real life, treatments are known to show lower success rates.[12–14] To the best of our knowledge, this is the first daily practice study analysing to what extent advice resulting from following the treatment goal algorithm is followed in daily practice.

In the present study, physicians were unaware of the components of treatment goals (DLQI and PASI percentage) and therefore unaware of treatment failure or treatment success according to these goals. Although physicians were not using treatment goals, in the majority of visits physicians followed the treatment goals algorithm intuitively. This can be explained by the high effectiveness of biologics in most visits, so physicians did not have to make changes to treatment strategies according to treatment goals. If patients did not

Table 2 Treatment modifications during patient visits in the daily practice cohort BioCAPTURE; data are stated as n (%)

Treatment groups	Modify: PASI 50 and PASI 50–75+ DLQI > 5 N = 162 (41%)	Continue: PASI 50–75+ DLQI ≤ 5 and PASI ≥ 75 N = 233 (59%)
No modification	103 (64%) visits	194 (83%) visits
Modification	59 (36%) visits; 61 modifications	39 (17%) visits; 40 modifications
1. Dose increase of		
Biological therapy	24	7
Conventional systemic therapy	3	0
Both	1	0
2. Dose decrease of		
Biological therapy	3 (1 according to label)	20 (12 according to label)
Conventional systemic therapy	4	6[a]
Both	0	0
3. Cessation of		
Biological therapy	0	1[b]
Conventional systemic therapy	2[b,c]	1[d]
2. Addition of		
Conventional systemic therapy	3	2
Intensive topical therapy	1[e]	0
Both	0	0
3. Switching therapy to		
Biological therapy	11	0
Conventional systemic therapy	1	0
Intensive topical therapy	0	0
4. Other	8[f]	3[f]

[a]One patient also restarted biological therapy after an upper respiratory tract infection; [b]due to desire for pregnancy; [c]one patient had a dose decrease of biologic and stopped conventional systemic therapy; [d]due to adverse effects (somnolence); [e]this patient also had a treatment interruption of biological therapy due to liver function abnormalities; [f]interruption or restart of biologic or systemic combination therapy due to, e.g. flu, urinary tract infection, other infections, liver function abnormalities.

reach treatment goals, it was shown that, in the majority of visits, physicians preferred to continue treatment without modification, so that is where there might be 'room for improvement'.

Achieving treatment success seems important for patients with psoriasis in order to reach a sufficient QoL. Using data from randomized clinical trials, Mattei *et al.*[15] have recently shown that patients treated with biological therapies have better QoL scores in the PASI 75 group.[15] The same results were seen in the daily practice situation in the present study. Patients with a PASI 75 response had better QoL scores more frequently, compared with patients in the remaining groups. Nineteen per cent of visits with a DLQI score showed low QoL (DLQI > 5) in the PASI 75 group compared with about 35–40% in the other two groups. Fifty per cent of DLQI scores were 0 in the PASI 75 group, indicating optimal QoL, compared with only 7% in the PASI 50 group. These results strengthen the definition of treatment success in the treatment goals, i.e. achieving a PASI 75 response compared with baseline. It must be noted that 19% of the available DLQI scores in the group achieving PASI 75 indicated low QoL. It might be of interest to establish what needs are not fulfilled for these patients.

We analysed whether baseline PASI scores influenced the possibility for patients to achieve treatment goals. Patients with high baseline PASI scores might achieve treatment success, and therefore treatment goals, more easily compared with patients with low baseline PASI scores, as these are expressed with a relative measure. This is especially important in the comparison between patients naive or nonnaive (switchers) for biologics, as the latter group often starts with a lower baseline PASI. Median baseline PASI score at the start was compared between groups Modify and Continue and was significantly lower for group Modify ($P = 0{\cdot}004$), although scores differed by only 1·7. This difference is small and will probably not explain why patients end up in group Modify or Continue. In the current treatment goals there is no differentiation between naive and nonnaive patients.

Our cohort showed that in group Modify, median DLQI was similar between patient visits with a treatment modification, compared with visits without a treatment modification. Hence, in daily practice in which treatment goals were not being implemented, the decision to modify therapy seems not to be influenced by the patient's perceived QoL. It might therefore be worthwhile to conduct DLQI questionnaires prior to the clinical visit in order to identify those patients with a low QoL to optimize their care.

As shown, there is considerable 'room for improvement' in the care of patients with psoriasis. Optimized treatment might be achieved by the consequent application of treatment goals. In this respect, lessons can be learned from previous studies in

rheumatoid arthritis, hypertension and diabetes.[16–19] The TICORA study for tight control in rheumatoid arthritis showed that a strategy of intensive outpatient management compared with routine daily practice improved disease activity and QoL at no additional costs. However, mixed results are seen in diabetes care.[20] Furthermore, implementation research in the field of rheumatology has shown that there are many reasons not to modify treatment while treatment goals advise to do so.[21] These findings may also apply to the field of dermatology. Possible factors include the presence of comorbidities, comedication, safety issues, number of available treatments left, not being aware of PASI percentages and DLQI scores, and reticence in physicians and patients.

The current treatment goals flowchart does not incorporate dose decreases in patients who meet criteria for continued treatment without modification. Evidence for dose decrease of biologics beyond the label is scarce in the field of psoriasis. It would be worthwhile to focus on this issue in future studies in order to decrease costs and improve safety.

Other barriers to implementing treatment goals might include the requirement that physicians should assess PASI scores and conduct DLQI measurements during patient visits. This requires optimal logistics and a time effort from physicians. Therefore it seems important to analyse further the impact of implementation of treatment goals on the care of patients with psoriasis.

A limitation of the present study is that topical treatments in combination with biologics were used as well, but not analysed in this study because data on nonintensive topicals were not completely recorded in the database. Another limitation is that there were missing data from DLQI questionnaires, which could lead to responder bias. However, the percentage of missing data was similar between groups. The strengths of this study are the inclusion of different clinical centres and doctors (both academic and nonacademic), the daily practice environment itself, and the 'blindedness' of doctors for DLQI and PASI scores.

This study addresses European treatment goals in daily clinical practice. Results show that in daily practice in which treatment goals were not yet implemented, physicians usually followed treatment goals intuitively in visits in which treatment goals were achieved. On the other hand, in patients with suboptimal response to therapy, frequently the same therapeutic regimen was continued. This shows an urgent need for identification of barriers to using treatment goals and the need for implementation studies as this might increase the rate of treatment success and the number of patients with psoriasis with optimal QoL on systemic therapies including biologics in daily clinical practice.

Conflicts of interest

J.Z. carries out trials for AbbVie, Janssen and Sciderm, and has received reimbursement for attending a symposium from AbbVie. J.M.P.A.v.d.R. carries out clinical trials for AbbVie and Janssen, has received speaking fees from AbbVie and reimbursement for attending a symposium from Janssen and AbbVie. P.C.M.v.d.K. serves as a consultant for Merck Sharp Dome, Celgene, Centocor, Allmirall, UCB, Pfizer, Sofinnova, AbbVie, Actelion, Galderma, Novartis, Janssen-Cilag, Ely Liley, Amgen, Mitsibishu and LEO Pharma; and receives research grants from Centocor, Pfizer, Merck Sharp Dome, Merck Serono, AbbVie and Philips Lighting. E.M.G.J.d.J. has received research grants for the independent research fund of the Department of Dermatology of University Medical Centre St Radboud Nijmegen, the Netherlands from Merck-Serono, Wyeth, AbbVie, Pfizer and Janssen, and has acted as consultant and/or paid speaker for and/or participated in research sponsored by companies that manufacture drugs used for the treatment of psoriasis including AbbVie, Janssen, MSD and Pfizer. M.D.N. serves as a consultant for Janssen. W.P.A. served as a consultant for AbbVie and Janssen and travelled with Pfizer, AbbVie and Janssen to medical congresses for 50% of the fees. The other authors state no conflicts of interest.

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