Patient-reported outcomes are important elements of psoriasis treatment decision making: A discrete choice experiment survey of dermatologists in the United States

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Background: Psoriasis Area and Severity Index (PASI) response rates have been the benchmark for evaluating treatment efficacy in trials involving moderate-to-severe psoriasis.

Objective: To understand how dermatologists assess biologics and which trade-off rules they apply when planning psoriasis treatment.

Methods: Two online surveys of 130 and 129 US dermatologists (surveys 1 and 2, respectively) were conducted with use of direct and indirect elicitation via discrete choice experiment. Respondents were asked to choose hypothetical biologics on the basis of 6 attributes (a ≥75% reduction from baseline in PASI score or a ≥90% reduction from baseline in PASI score, infection risk, dosing frequency, and 3 patient-reported outcomes [PROs] [relief of depression, relief of itching, and impact on usual activities]).

Results: Most dermatologists (74% in survey 1 and 76% in survey 2) reported using both PASI and PROs when selecting a biologic. PASI response rate was the most important attribute (35%-38% of overall decision weight), whereas combined PRO attributes had similar importance (36% of decision weight). Infection risk and dosing frequency influenced the decision to a lesser extent.

Limitations: Potential bias in considering 3 PROs versus 1 PASI rate and 1 safety attribute.

Conclusion: PASI is most important for dermatologists selecting biologics, but PROs are also considered, especially when PASI response rate is similar between treatments. PRO data should be collected in trials involving moderate-to-severe psoriasis. (J Am Acad Dermatol 2019;80:1650-7.)

Key words: biologics; patient-reported outcomes; psoriasis; Psoriasis Area and Severity Index; treatment decision making.

The physician-evaluated Psoriasis Area and Severity Index (PASI) estimates psoriasis severity on the basis of lesion characteristics and is the most frequently used primary end point for evaluating treatment efficacy in clinical trials involving moderate-to-severe psoriasis.[1,2] Despite its importance as an efficacy measure, the PASI does not capture the impact of psoriasis on patients' lives. Psoriasis can exert multiple burdens beyond changes in appearance, including symptoms such as itching and pain; limitations on the ability to conduct usual activities; interference with sleep, sexual function, and relationships; and increased risk of mental health disorders such as anxiety and depression.[3-8] As a result, patient-reported outcomes (PROs) have been increasingly evaluated in trials involving moderate-to-severe psoriasis to complement objective disease measures such as the PASI.[6,9] PROs commonly incorporated into clinical trials include self-assessments of psoriasis-related symptoms and health-related quality of life (HRQoL), which are typically evaluated by using the Dermatology Life Quality Index.[10-12]

Clinical trials have frequently used a 75% or greater reduction from baseline in PASI score (PASI 75 response) as a measure of success for the treatment of moderate-to-severe psoriasis.[13-15] However, there has been recognition that a 90% or greater decrease from baseline in PASI score (PASI 90 response) may be an even more relevant treatment response because it is more highly correlated with improvements in HRQoL, including a Dermatology Life Quality Index score of 0 or 1, which implies no effect of skin disease on HRQoL.[16,17] PASI 90 is considered a "measure of optimal response" by the American Academy of Dermatology[18] and the threshold of treatment success by the European Medicines Agency.[19]

In clinical practice, dermatologists are likely to consider multiple factors when choosing a biologic for patients with moderate-to-severe psoriasis, including efficacy, safety (both short-term tolerability and long-term risks), convenience, cost, mechanism of action, and patient preference.[20] Although efficacy is clearly a key factor, little is known about the role that PROs play in the treatment decision—making process. Selection among different treatments that have multiple attributes to consider is a complex cognitive process that cannot be adequately described by simply asking respondents to rate or rank the attributes most important to them.[21,22] Discrete choice experiments have been developed specifically to provide information about how individuals approach such choices. This methodology is based on random utility theory, which asserts that decision makers are willing to accept trade-offs among different product features (eg, drug characteristics) and that trade-offs are an indication of the relative value of the features.[23] For example, some individuals may be willing to tolerate mild-to-moderate side effects to achieve better efficacy, whereas others may not. There has been a rapid increase in the application of discrete choice surveys in health care research,[24] with successful use in measuring preferences for a diverse range of health interventions.[25-28]

Using this methodology, we explored the importance of PROs compared with a clinical objective measure of psoriasis severity (the PASI) in the dermatologist's decision to prescribe a biologic treatment for moderate-to-severe psoriasis. The impacts of safety and dosing frequency were also assessed, given their demonstrated relevance to treatment choice in previous studies.[29,30]

METHODS
Study design
Two online surveys (1 using PASI 75 response and 1 using PASI 90 response) were conducted; they involved dermatologists recruited from a large, representative US panel. Survey 1 was conducted during March 2017 and included 130 dermatologists; survey 2 was conducted during August 2017 and included 129 dermatologists. Both surveys used identical methods, namely direct and indirect elicitation via discrete choice experiment (conjoint). For survey 1, the respondents were selected on the basis of a random sampling procedure, whereas for survey 2, quota sampling was used to match the respondents' profile in the first survey. Dermatologists or internists specializing in dermatology were eligible to participate if they had been in clinical practice for at least 3 years, were 30 to 65 years of age, spent at least 50% of their time in the management and

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CAPSULE SUMMARY

- Physician-evaluated measures of psoriasis severity are the primary assessments in psoriasis trials; however, US dermatologists also consider patient-reported outcome data when selecting a biologic for patients with moderate-to-severe psoriasis.

- Patient-reported outcome evaluations should be integrated into psoriasis clinical trials to obtain the information needed to facilitate treatment decision making.

treatment of patients, were personally responsible for the management and initiation of conventional systemic and biologic treatments for patients with moderate-to-severe psoriasis, and had treated at least 5 patients with moderate or severe plaque psoriasis within the previous month.

Survey approach

Conjoint analysis was used in both surveys. Conjoint analysis is a decomposition method in which the values for attributes of an intervention are derived from an overall score for a profile consisting (conjointly) of 2 or more attributes.[31] A well-designed series of hypothetical product scenarios can isolate the independent effects of each attribute on product selection. In designing the present study, the authors followed the International Society for Pharmacoeconomics and Outcomes Research good research practices for conjoint analysis.[23]

Respondents were asked to consider the best medication choices for 2 types of patients: both 45 years old with moderate-to-severe psoriasis for 20 years, previous failure of conventional systemic psoriasis therapy or apremilast, and no concomitant psoriatic arthritis. One type of patient had no previous exposure to biologic therapy, whereas the other type was currently undergoing a first-line biologic therapy. Respondents had to repeatedly choose from among 3 different hypothetical products to identify the product that they would prefer and to then indicate whether they would prescribe the selected product to patients with moderate-to-severe psoriasis (survey available on request). The product profiles were defined by 6 different attributes, including the PASI (PASI 75 for survey 1 and PASI 90 for survey 2), 3 PROs, a safety outcome based on the risk of infection, and dosing frequency (Table I). The levels of these attributes varied from high, medium, or low to, in some cases, no available data from randomized controlled trials for each product presented to the respondents (Table I), whereas cost (copayments) and duration of therapy were assumed to be the

same across products. Attribute levels were based on changes from baseline to week 52 after initiation of treatment. Survey 1 and survey 2 used PASI 75 and PASI 90 efficacy attributes, respectively, to ensure that results did not depend on the level of change from baseline PASI score.

Psoriasis can affect diverse dimensions of patient lives.[7] The number of PRO attributes assessed in our research was limited to 3, however, to reduce bias favoring PROs over non-PRO attributes and ensure that the total number of attributes did not exceed 6, above which amount discrete choice experiments become more challenging for respondents.[22] The PRO attributes (ie, itching, depression, and ability to perform usual activities) were selected on the basis of authors' expert opinion and existing literature regarding the most patient relevant end points in this disease.[32,33] Itching has been identified as the most bothersome symptom by patients with psoriasis in large, multinational, population-based surveys.[7,32] Furthermore, 56% of patients with psoriasis report that they would like to feel less depressed, and 68% would like to be able to engage in normal leisure activities, according to a World Health Organization study.[8] Improvements in scaling and flaking are also outcomes important to patients, but because they are part of the same domain as itching (ie, symptoms), they were not selected. It should be noted that associations exist among efficacy outcomes of psoriasis treatment and therefore among some of the attributes assessed in this analysis. Associations between improvements in PASI score and either itching or HRQoL exist but do not reach levels indicating very high correlation (ie, a correlation coefficient >0.9).[34] Itching may be an even stronger determinant of patient-perceived quality of life than PASI score is.[35] Therefore, the attributes evaluated here can be considered in the same conjoint analysis.

To ensure that attribute levels were considered clinically realistic by the respondents, the 2 highest PASI and PRO attribute levels were loosely derived from the results of the recent CLEAR study, which was a randomized, controlled, head-to-head trial comparing secukinumab and ustekinumab in patients with moderate-to-severe psoriasis.[11,36]

Analysis

Hierarchical Bayes estimation was used to calculate the individual parameter estimates by making use of a joint parameter distribution for all respondents. The utility is a measure of the attractiveness of a product profile (ie, the higher the utility, the more attractive the product). Importance scores were calculated on the basis of attribute ranges of utilities,

Table I. Attribute levels used in discrete choice experimentation

Attribute	Levels (high, medium, low)*
Percentage of patients who achieved a reduction in PASI score from baseline of at least 75% (survey 1, PASI 75) or 90% (survey 2, PASI 90)	Survey 1: 90%, 75%, or 60% Survey 2: 75%, 60%, or 45%
Percentage of patients who achieved complete relief of itching	65%, 50%, 35%, or no data captured in RCT
Percentage of patients whose difficulties in conducting usual activities resolved	90%, 75%, 60%, or no data captured in RCT
Percentage of patients whose depression resolved	65%, 50%, 35%, or no data captured in RCT
Safety	No increased risk of infection; 1 additional superficial *Candida* infection per 100 patient-years over the baseline rate; or hepatitis B test required before treatment initiation AND 1 additional superficial *Candida* infection per 100 patient-years over the baseline rate
Dosage (administration by subcutaneous injection)	1 shot every 3 mo; 1 shot/wk for the first 4 wk and 1 shot/mo afterward, or 1 shot/wk for the first 3 mo and 1 shot/mo afterward

PASI, Psoriasis Area and Severity Index; *RCT*, randomized controlled trial.
*Highest attribute levels would be hypothesized as the most desirable.

Table II. Respondent characteristics

Characteristic	Survey 1* (n = 130)	Survey 2* (n = 129)
Age, y, mean (SD)	46 (9.5)	45 (9.8)
Sex, n (%)		
Male	77 (59)	79 (61)
Female	53 (41)	50 (39)
Practice setting, n (%)		
Office/private practice—based	110 (81.5)	108 (83.7)
Academic hospital—based only	15 (11.1)	10 (7.8)
Community hospital—based only	1 (0.7)	3 (2.3)
Mixed physician	10 (7.4)	10 (7.8)
Specialized psoriasis clinic	1 (0.7)	1 (0.8)
Postresidency work experience, y, mean (SD)	14 (8.2)	14 (8.4)
Number of patients with psoriasis treated in past month, mean (SD)	79 (64.3)	96 (116.9)
Patients with mild psoriasis	30 (29.2)	33 (38.3)
Patients with moderate psoriasis	31 (23.7)	39 (48.7)
Patients with severe psoriasis	18 (21.2)	24 (42.8)
Percentage of time spent treating patients, mean (SD)	95 (6.0)	95 (5.9)

PASI, Psoriasis Area and Severity Index; *PASI 75*, percentage of patients who achieved a reduction in PASI score from baseline of at least 75%; *PASI 90*, percentage of patients who achieved a reduction in PASI score from baseline of at least 90%; *SD*, standard deviation.
*Survey 1 included PASI 75 and survey 2 included PASI 90 as the objective efficacy measure.

assuming that an attribute with a larger range of utilities between the worst and best potential attribute levels was more important. Because the model calculates the utility of each level for all attributes, the model allows estimation of the total attractiveness of a product profile. Specifically, share of preference (SoP) simulations were used to predict each respondent's preference for a certain product profile compared with an alternative product profile. The SoP of a specific product profile was the percentage of respondents with higher utilities for the product than for the alternative.

RESULTS

The characteristics of the respondents in survey 1 and survey 2 were similar. Respondents were mostly office/private practice—based and had been practicing for a mean of 14 years after residency (Table II). Overall, they reported spending 95% of their time treating patients versus engaging in other
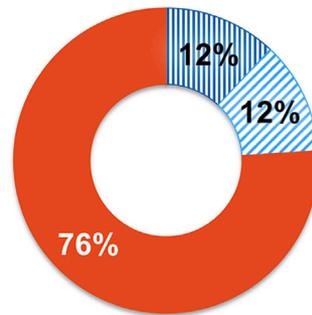
Question: With which statement do you agree the most when you evaluate the efficacy of new biologic treatments against psoriasis in your daily practice?

▥ I use exclusively PASI reduction (e.g. PASI 75, PASI 90, PASI 100)

▨ I use exclusively patient-reported outcomes (e.g. psoriasis symptoms)

🟥 **I use both PASI data and patient-reported outcomes (e.g. psoriasis symptoms)**

Fig 1. Efficacy evaluation criteria of dermatologists for new biologic psoriasis treatments as revealed by results from survey 2. *PASI*, Psoriasis Area and Severity Index; *PASI 75*, percentage of patients who achieved a reduction in PASI score from baseline of at least 75%; *PASI 90*, percentage of patients who achieved a reduction in PASI score from baseline of at least 90%; *PASI 100*, percentage of patients who achieved complete resolution in PASI score from baseline.

activities such as research, lecturing, publishing, or administrative tasks.

For direct elicitation responses, 76% of respondents in survey 2 reported using both PASI 90 and PROs when selecting a biologic treatment for moderate-to-severe psoriasis, whereas 12% used PASI data exclusively and the remaining 12% only used PRO data (Fig 1). Comparable results were obtained in survey 1, in which 74% of respondents reported using both PASI 75 and PROs when selecting a biologic treatment (survey 1 results available on request).

No statistically significant differences were observed between the 2 types of patients (ie, biologic-naive or undergoing their first biologic therapy) with respect to responses, and therefore utility scores for both types of patients were combined in all analyses. Conjoint results from survey 1 and survey 2 were also similar. Because trials of newer-generation biologics for the treatment of moderate-to-severe psoriasis tend to use the PASI 90 response rate as the primary efficacy end point instead of PASI 75, we have reported only results from survey 2. As would be expected, higher physician preference (or higher average utility score) was reported for greater levels of each attribute. In survey 2, respondents expressed much greater preference for a PASI 90 response rate of 75% than for a rate of 60% (average utility

scores, 101.3 vs 0.9). Similarly, respondents had greater preference for the highest level of resolution of difficulties with usual activities (the 90% vs 75% rates had average utility scores of 34.2 vs 8.4), resolution of itching (the 65% vs 50% rates had average utility scores of 18.3 vs 4.8), and resolution of depression (the 65% vs 50% rates had average utility scores of 20 vs 6.3). Notably, the respondents preferred to have PRO data captured in a randomized clinical trial irrespective of the attribute level. Finally, a safety profile with no increased risk of infection was preferred to having 1 additional superficial *Candida* infection per 100 patient-years over baseline (average utility scores, 47.1 vs 0.7).

Considering the relative importance of each attribute in the treatment decision−making process, PASI score was the most important attribute, accounting for 38% of the overall decision weight in survey 2 (Fig 2). When combined, the PRO attributes were about as important as the PASI score, accounting for 36% of the overall weight. Each of the 3 PROs carried a similar level of importance, with solving difficulties in usual activities, solving depression, and providing complete relief of itching accounting for 14%, 11%, and 11% of the overall weight, respectively. Safety (risk of infection) accounted for 18% of the overall weight, whereas dosing frequency was considered a less important attribute, accounting for 8% of the overall weight.
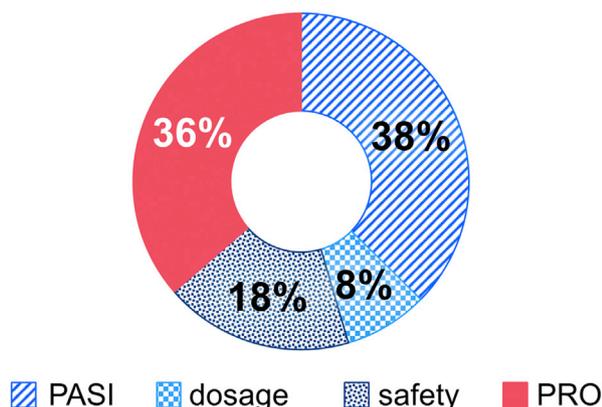
Fig 2. Weights of different attributes in treatment decision making based on results from survey 2. *PASI*, Psoriasis Area and Severity Index; *PRO*, patient-reported outcome.

In the first set of SoP simulations, hypothetical products with the same PASI score, safety, and dosage attributes but with different PRO attribute levels were compared (simulations 1 and 2). Products with medium or high PRO attribute levels were preferred to products for which no PRO data were available. A product with a PASI 90 response rate of 75% and either medium-level PRO attributes (SoP, 69.4%) or low-level PRO attributes (SoP, 59.5%) was preferred to a product with a PASI 90 response rate of 60% and high-level PRO attributes (second set of simulations, 3 and 4). The third set of simulations considered PASI versus safety. In 1 of these (simulation 7), a product with a PASI 90 response rate of 60% and 1 additional superficial *Candida* infection per 100-patient years over baseline was preferred over a product with a PASI 90 response rate of 45% and no increased risk of infection (SoP, 72.5%). The fourth set of simulations, which considered PASI versus dosing frequency, showed that higher levels of PASI 90 response are preferred regardless of the dosing frequency level. Finally, when multiple attributes were varied, a product having a PASI 90 response rate of 75% and medium-level attributes for PROs, safety, and dosing frequency was preferred over a product having a PASI response rate of 60%, high-level attributes for PROs and safety, and a dosing frequency of 1 shot per week for the first 3 months and then 1 shot per month afterward (SoP, 56.3%). Comparable results were obtained for simulations of survey 1 with use of PASI 75 levels (complete SoP simulation results available on request).

DISCUSSION

The findings from these surveys confirm that objective improvement in disease severity is the crucial determinant for US dermatologists when selecting a biologic treatment for patients with moderate-to-severe psoriasis. The results of survey 1 (using PASI 75) and survey 2 (using PASI 90) were consistent; in both surveys, the PASI was identified as the single most important attribute in the decision-making process. However, the 3 PRO attributes, when combined, were as important as the PASI alone. These results indicate that PROs are also considered relevant data when making treatment decisions in moderate-to-severe psoriasis.

Average utility scores for different attribute levels were similar regardless of whether hypothetical patients were biologic-naive or already receiving a first biologic, or whether PASI 75 (survey 1) or PASI 90 (survey 2) response rate was considered. These results suggest that dermatologists evaluate the characteristics of a biologic in a similar manner irrespective of a patient's level of treatment experience or the efficacy benchmark used.

SoP simulations 3 and 4 illustrate the preference for higher PASI response rates as compared with more desirable PRO attributes. A hypothetical product with a high PASI response rate combined with low- or medium-level PRO attributes had a greater SoP than a product with medium-level PASI and high-level PRO attributes, indicating that a superior PRO profile alone would not compensate for a lower PASI response. For a given level of PASI, SoP was much greater for products with medium- or high-level PRO attributes than for products without PRO data (simulations 1 and 2). These findings illustrate the value of collecting PRO data in clinical trials for moderate-to-severe psoriasis.

Despite the inherent limitations of any survey-based research, the methodology utilized in our surveys is well established in the academic literature as a credible representation of the human decision-making process.[21,22] Findings from this approach, which is based on presenting survey respondents with hypothetical choice scenarios, are less likely than direct questioning techniques to result in survey respondents voicing abstract, normative principles on what should drive prescribing and are more likely to reflect the complex reality of how they compare multiple therapies with a mix of different attributes. Consistent with earlier research on the treatment preferences of patients,[29] the present study indicated that dermatologists also value improvements in PROs such as symptom reduction, functional enhancement, and improved mental health when evaluating psoriasis therapies. Also consistent with previous work, we found dosing frequency to be less important than efficacy in the treatment decision—making process of dermatologists.[30]

The main limitation of this study was the small number of PRO attributes selected for evaluation, which resulted in the exclusion of some domains known to be important to patients with moderate-to-severe psoriasis (eg, pain, sexual dysfunction).[3] A second limitation is that varying 3 PRO attributes versus only 1 PASI score at a time and only 1 safety attribute (risk of infection) may have introduced bias favoring the importance of the PROs. Further, given that the only safety attribute evaluated was risk of infection, trade-offs likely to be made in the real world between higher PASI and additional potential safety risks could not be assessed. Price differences were also excluded, although this is an important consideration in prescribing biologics in the real world.

In conclusion, the PASI response rate remains the most important attribute utilized by dermatologists to decide which biologic treatment to prescribe for patients with moderate-to-severe psoriasis. Our findings suggest that dermatologists may be willing to accept some increased risk of infection (namely, 1 additional superficial *Candida* infection per 100 patient-years over baseline) to have a therapy with a higher PASI response rate, a willingness that might be explained by the realization that patients with psoriasis care deeply about getting rid of the lesions. PROs are seen as an additional relevant source of information to assist decision making, especially when efficacy (PASI response rate) is similar between products. Accordingly, these results support the utility of collecting PRO data in psoriasis clinical trials.

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