The Relationship Between Patient Acceptable Symptom State and Disease Scores in Psoriasis

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Abstract

Patient acceptable symptom state (PASS) is a patient-reported outcome that reflects patient's perspective well. The relationship between the PASS and disease scores in psoriasis has not been described. This study of 198 patients with psoriasis, assessed PASS using a binary question on patient's feeling on their symptom. The disease scores including Psoriasis Area and Severity Index (PASI), Body Surface Area (BSA) affected by lesions and other patient characteristics were collected. Logistic regression was used to investigate the associations. 71.4% patients with mild psoriasis based on PASI and 76.3% based on BSA considered their symptom state acceptable. Female (adjusted OR=0.47; 95% CI: 0.42–0.92) and patients with exposed skin (head, neck, and hands) involved (adjusted OR=0.38; 95% CI: 0.19–0.76) were less likely to report acceptable symptom state. Receiver-Operating Characteristics curve showed that both PASI and BSA have limited capability in differentiating acceptable symptom state in psoriasis, which further indicated the unique value of PASS in the management of psoriasis.

Introduction

Psoriasis is a common chronic, immune-mediated inflammatory skin disease characterized by red and scaly plaques with significantly negative impact on quality of life of patients, affecting over 125 million people globally[1–3]. Psoriasis Area and Severity Index (PASI) based on severity and area of psoriatic lesions is a common tool to assess the severity of psoriasis[4]. The body surface area (BSA) affected by psoriasis is another common tool that evaluates area of psoriasis lesion only[5,6]. Both tools have corresponding thresholds in differentiating the severity of disease from the clinician's perspective. Evaluation of the effectiveness of intervention in psoriasis is mostly determined by the change of PASI or BSA score from baseline. However, these changes does not necessarily represent an important improvement from the patient's perspective. Therefore, taking into consideration the patient perspective is needed to evaluate the effect of treatment in addition to the change of score. Some patient-reported measures are commonly used in psoriasis, such as the Dermatology Life Quality Index (DLQI) and EuroQol 5-Dimension (EQ-5D)[7–9]. However, these tools focus on specific aspects of health-related quality of life (HRQoL), and these aspects do not necessarily reflect the overall impact of the disease and patient acceptability. Moreover, health utility-related measures like EQ-5D demonstrates strong ceiling effect and is not sensitive for mild disease condition.

The patient acceptable symptom state (PASS) is a patient-reported measure of well-being[10–12], focusing on the feeling about their symptoms and representing a clinically relevant outcome. The relationship between PASS and disease activity scores or patient-reported outcomes had been evaluated in many diseases, such as ankylosing spondylitis (AS)[10,11], rheumatoid arthritis (RA)[13], and psoriatic arthritis (PsA)[14], lichen planus[15], scleroderma[16,17], etc. However, the PASS and its association with objective measures of psoriasis has not been described yet.

The objectives of the current study were to describe the PASS across different severities of psoriasis, investigate factors associated with the PASS, and determine the cut-off points of PASI and BSA for PASS.

Methods

Study design and patients

This was a cross-sectional study in patients with psoriasis vulgaris. Patients aged 18 and above who were admitted to the dermatology department of Xiangya Hospital during September and November 2020 were consecutively enrolled. Participants who did not complete questions on the patient-reported outcomes were contacted by phone. Informed consent was obtained from all patients before the investigation. The study followed the Declaration of Helsinki and was approved by the institutional research ethics boards of Xiangya Hospital (approval number: 2018121106).

Data collection

The PASS was assessed by a binary answer to the following question: “Think about all the ways your psoriasis has affected you during the last 48 h. If you were to remain in the next few months as you were during the last 48 h, would this be acceptable to you? A “yes” response to the question was considered as the achievement of the PASS (PASS-Y), and “no” corresponding to PASS-N[14].

PASI and BSA affected by psoriasis were evaluated by a trained research nurse. The severity (mild, moderate, and severe) of psoriasis was determined by the both score as less than 3, 3 to 10, and more than 10 respectively. Meanwhile, locations of psoriatic lesion were recorded, and if head, neck, or hands was involved, an “exposed lesion” was endorsed.

Other data collected included age, sex, psoriasis duration, education level, comorbidities (hypertension, hyperlipidemia, and diabetes), cigarette smoking, and alcohol drinking. Comorbidities were determined by medical records and self-reported history of disease. Cigarette smoking was defined as having smoked at least 100 cigarettes in one’s lifetime, and alcohol drinking was defined as consumption of 30g of alcohol per week for at least one year [18]. Height and weight were measured by the research nurse in a standard way. Body mass index (BMI) was calculated as weight /squared height (kg/m^2). Overweight and obesity were defined by the cut-offs of 24 kg/m^2 and 28 kg/m^2, respectively.

Statistical analysis

Continuous variables with normal distribution were expressed as mean ± standard deviation (SD). Categorical variables were calculated and summarized as counts (percentages). The *t* test statistic and Pearson chi-square tests or Fisher exact tests were used to analyze differences in continuous and categorical variables, respectively. The associations of PASS with the disease score and patients’ clinical characteristics were analyzed by multivariate logistic regression with adjustments for variables with *P* value < 0.05 in the univariate analysis. Odds Ratio (OR) and 95% confidence interval were used to present the effect size of the associations. Receiver operating characteristics (ROC) curve was used to determine the PASI/BSA thresholds for PASS based on the maximal Youden’ index for sensitivity and specificity[19]. A *P* value less than 0.05 was deemed statistically significant. The data were analyzed with SPSS 23 (IBM, SPSS Statistics 23).

Results

A total of 262 patients met the inclusion criteria, and 64 refused to participate or failed to contact successfully (34 males and 30 females). Table 1 summarizes the demographic characteristics and disease characteristics of the 198 participants who completed this study. The mean age was 41.9 ± 12.6 years, 55 (27.8%) were females, and the mean psoriasis duration was 10.2 ± 8.6 years. PASI, BSA, exposed skin involved, and educational level were significantly different between PASS status. No statistical differences were found for comorbidities, smoking, alcohol drinking, and body mass index between PASS status. In total, the proportion of patients who responded “yes” to the PASS was 56.6%, and 71.4% patients with mild psoriasis (defined by PASI) considered their symptom state acceptable, compared with 48% and 14% in moderate and severe psoriasis, respectively. Similarly, 76.3% patients with mild psoriasis (defined by BSA) considered their symptom state acceptable, compared with 28% and 23% in moderate and severe psoriasis, respectively.

Table 1
Patient characteristics by PASS status.

Characteristics	PASS-N (n = 86)	PASS-Y (n = 112)	*P*
Age (mean ± SD)	43.3 ± 12.1	40.7 ± 13.0	0.392
Female, n (%)	31 (36.0)	24 (21.4)	0.023
Psoriasis duration (mean ± SD)	9.2 ± 8.3	10.9 ± 8.8	0.115
PASI (mean ± SD)	8.0 ± 6.9	5.0 ± 6.1	< 0.001
BSA, % affected by psoriasis (mean ± SD)	11.3 ± 12.2	7.4 ± 12.3	< 0.001
PASI, n (%)			0.002
Mild (< 3)	20 (28.6)	50 (71.4)	
Moderate (≥ 3-<10)	42 (46.7)	48 (53.3)	
Severe (≥ 10)	24 (63.2)	14 (36.8)	
BSA, n (%)			< 0.001
Mild (< 3%)	19 (23.7)	61 (76.3)	
Moderate (≥ 3% to < 10%)	35 (55.6)	28 (44.4)	
Severe (≥ 10%)	32 (58.2)	23 (41.8)	
Exposed skin involved (head, neck and hands), n (%)	70 (81.4)	62 (55.4)	< 0.001
Educational level, n (%)			0.040
Primary / middle school	38 (44.2)	53 (47.3)	
High school	28 (32.6)	31 (27.7)	
College or above	20 (23.2)	28 (25.0)	
Comorbidities, n (%)			
Hypertension	5 (5.8)	8 (7.1)	0.708
Hyperlipidemia	14 (16.2)	21 (18.8)	0.651
Diabetes	6 (7.0)	8 (7.1)	0.964
Smoking, n (%)	44 (51.2)	54 (48.2)	0.681
Alcohol drinking, n (%)	14 (16.3)	17 (15.2)	0.833

PASS, patient acceptable symptom state.

P value by univariate logistic regression model.

Characteristics	PASS-N (n = 86)	PASS-Y (n = 112)	*P*
Body Mass Index (kg/m^2), n (%)			0.615
<24	49 (57.0)	57 (50.9)	
24-27.9	28 (32.6)	39 (34.8)	
≥ 28	9 (10.5)	16 (14.3)	
PASS, patient acceptable symptom state.			
P value by univariate logistic regression model.			

As shown in Table 2, multivariable analysis indicated that female (AOR = 0.47; 95% CI: 0.42–0.92) and patients with exposed skin involved (AOR = 0.38; 95% CI: 0.19–0.76) were less likely to report acceptable symptom state. To further examine the associations, subgroup analysis by different severities based on PASI or BSA were performed. Area of psoriatic lesion showed a larger effect on PASS status in mild psoriasis (AOR = 0.62; 95% CI: 0.42–0.92) compared with that in moderate and severe psoriasis. Exposed skin involved was significantly associated with less acceptability across severity groups in a dose-response manner (mild, AOR = 0.40; moderate, AOR = 0.36; severe, AOR = 0.24) (Table 3). Subgroup analysis by sex showed no significant differences in effect sizes (data not shown).

Table 2
Multivariable analyses of the relationship of PASS status with patient characteristics.

	PASS-N	PASS-Y		
Variables	OR	OR (95% CI)	AOR (95%CI) [a]	*P*
Age	1	0.98 (0.96, 1.01)	0.98 (0.96, 1.01)	0.164
Female	1	0.48 (0.26, 0.91)	0.47 (0.42, 0.92)	0.027
Psoriasis duration	1	1.02 (0.99, 1.06)	1.03 (0.99, 1.07)	0.187
PASI	1	0.93 (0.88, 0.97)	0.92 (0.83, 1.02)	0.118
BSA	1	0.97 (0.95, 1.00)	1.02 (0.97, 1.07)	0.495
Exposed skin involved	1	0.28 (0.15, 0.55)	0.38 (0.19, 0.76)	0.006
PASS, patient acceptable symptom state. OR: unadjusted odds ratio. AOR: adjusted odds ratio. CI: confidence interval. PASI: psoriasis area severity index. BSA: body surface area.				
[a] Adjusted for sex, PASI, BSA, exposed skin involved, educational level.				
P value for adjusted OR, estimated from multivariable logistic regression model.				

Table 3
Multivariable analyses of the relationship of PASS status with patient characteristics by different severity based on PASI or BSA.

	Severity					
	Mild (PASI < 3 or BSA<%3)		Moderate (PASI ≥ 3 to < 10 or BSA≥%3 to <%10)		Severe (PASI ≥ 3 or BSA≥%3)	
Variables	AOR (95%CI)	*P*	AOR (95%CI)	*P*	AOR (95%CI)	*P*
Age	0.98 (0.94, 1.02)	0.397	0.98 (0.95, 1.01)	0.177	0.99 (0.93, 1.04)	0.581
Female	0.62 (0.19, 2.06)	0.434	0.47 (0.19, 1.15)	0.099	0.69 (0.18, 2.62)	0.587
Psoriasis duration	1.05 (0.98, 1.13)	0.157	1.01 (0.96, 1.07)	0.651	1.04 (0.96, 1.12)	0.321
PASI	1.03 (0.77, 1.37)	0.869	1.08 (0.89, 1.30)	0.459	0.97 (0.86, 1.11)	0.694
BSA	0.62 (0.42, 0.92)	0.019	0.97 (0.89, 1.06)	0.520	1.03 (0.97, 1.09)	0.384
Exposed skin involved	0.40 (0.13, 1.20)	0.102	0.36 (0.15, 0.90)	0.029	0.24 (0.05, 1.13)	0.071

PASS, patient acceptable symptom state. OR: unadjusted odds ratio. AOR: adjusted odds ratio. CI: confidence interval. PASI: psoriasis area severity index. BSA: body surface area.

[a] Adjusted for sex, PASI, BSA, exposed skin involved, educational level.

P value for adjusted OR, estimated from multivariable logistic regression model.

The threshold for PASI was 3.95 in differentiating psoriasis patients in an acceptable symptom state (PASS-Y) from those not (Fig. 1a). The area under the curve (AUC) was 0.671 (95% CI: 0.596–0.745) with a sensitivity of 0.67 and specificity of 0.60. The threshold for BSA was 2.85%, and the AUC was 0.662 (95% CI: 0.586–0.738) with a sensitivity of 0.79 and specificity of 0.54 (Fig. 1b).

Discussion

The current study brought important information on the relationship between the PASS and disease score in psoriasis. Most patients with mild or moderate psoriasis considered their symptoms acceptable. A dose-response relationship was identified in the association between the PASS status and severity of disease. In addition, female sex and exposed skin involved were risk factors for the acceptable status.

Both PASI and BSA showed limited capability in differentiating psoriasis patients in an acceptable symptom state from those not.

The clinician's and patient's perspectives could be different in terms of the severity of disease or therapeutic effect, and the discrepancy might not be conducive to the management of disease[14,20–22]. As a patient-reported measure, acceptable symptom state effectively reflects patient's perception on disease's impact on themselves. In our study, most patients with mild or moderate psoriasis considered their symptoms acceptable; this is consistent with the findings of studies in RA and PsA[13,14]. Mild severity indicates less time needed for skin care and less visibility of lesions. In addition, we examined the possible factors associated with PASS status, and found that females were less likely to report acceptable symptom state, and similar result was reported in patients who underwent ligament reconstruction[23]. Exposed skin involved also considerably affected patient's acceptable symptom state in our study. In contrast to musculoskeletal diseases such as RA and AS, psoriasis is a skin disease with evidently negative impact on appearance, and is thus more likely to cause psychological distress[24–26]. The degree of emphasis on smooth and beautiful skin in female is stronger than that in male. These characteristics might be the reasons why female and exposed skin involved are risk factors for PASS-N. Subgroup analysis also noted that the effect of exposed skin involved on PASS status was stronger as the severity increased. Patients with severe psoriasis may have larger areas of exposed skin lesion compared with moderate or mild psoriasis, as well as higher levels of systematic inflammation and metabolic disruption, resulting in effect modification statistically.

Through the ROC curve analyses, we determined the thresholds of PASI and BSA in differentiating PASS-Y from PASS-N was 3.95 and 2.85%, respectively. The cut-offs were within the moderate severity for PASI and mild for BSA. Previous studies reported the 75th percentile approach was also used to determine the thresholds of disease scores for PASS[11,23], but the ROC curve analyses may generate a more precise estimate owing to the thresholds defined by ROC curve analyses are based on the best trade-off for sensitivity and specificity[14]. Our results indicated that the PASI and BSA had limited capability in differentiating acceptable symptom state in psoriasis, and the sensitivity and specificity for the both scores were lower compared with previous studies in other diseases[13,14]. This indicates that cutaneous symptoms and disfigurement may contribute to acceptability which is not captured by the objective measure of psoriasis severity. Therefore, acceptability of patient symptoms should be taken into consideration in treatment decision-making processes in addition to the changes of PASI or BSA, patients who reported PASS-N should receive additional interventions to improve health-related outcome.

Other common patient-reported measures that are used in psoriasis include instruments for health-related quality of life, among which DLQI is the most frequently used[7,8]. However, the tool has weaknesses, such as disordered response thresholds, item bias, and psychometric properties[27]. The bio-psycho-social medical model is proposed as an integrated way to understand diseases[28], and the acceptability of patients is an outcome of multifaceted factors. Further studies on the association of PASS with other patient-reported measures in psoriasis are warranted.

This study has some limitations. First, selection bias might be introduced in a single-center hospital-based study that captures patients with severer disease status and stronger willingness to seek help. Second, patients may have different understanding on the single question that was used to assess the outcome. Third, more intermediate and modifiable factors for PASS should be investigated, such as psychological resilience, perceived stress, symptoms of depression and anxiety, and social support.

In conclusion, this study accentuated the importance of patient-reported measures, which should be taken into consideration in treatment decision-making processes. To our knowledge, this is the first study that described PASS and investigated the association of disease severity and patient characteristics with PASS in psoriasis. We found that patients with mild psoriasis had a high proportion of acceptable status, while female sex and exposed skin involved were factors for less acceptability. Poor discrimination capability of PASI and BSA further indicates the unique value of PASS in the management of psoriasis.

Declarations

Data Availability:

The datasets generated during and/or analyzed during the current study are available by request.

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Author’s contributions:

All authors contributed to the study conception and design. Material preparation, data collection and analysis: Qiaolin Wang, Wenhua Lu, Yan Luo, Minjia Tan, Yehong Kuang and Minxue Shen; writing: Qiaolin Wang; funding: Wu Zhu, Yehong Kuang and Minxue Shen; data interpretation/revision/final approval: all authors.

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Competing Interests Statement:

The authors declare that they have no conflict of interest.

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Figures

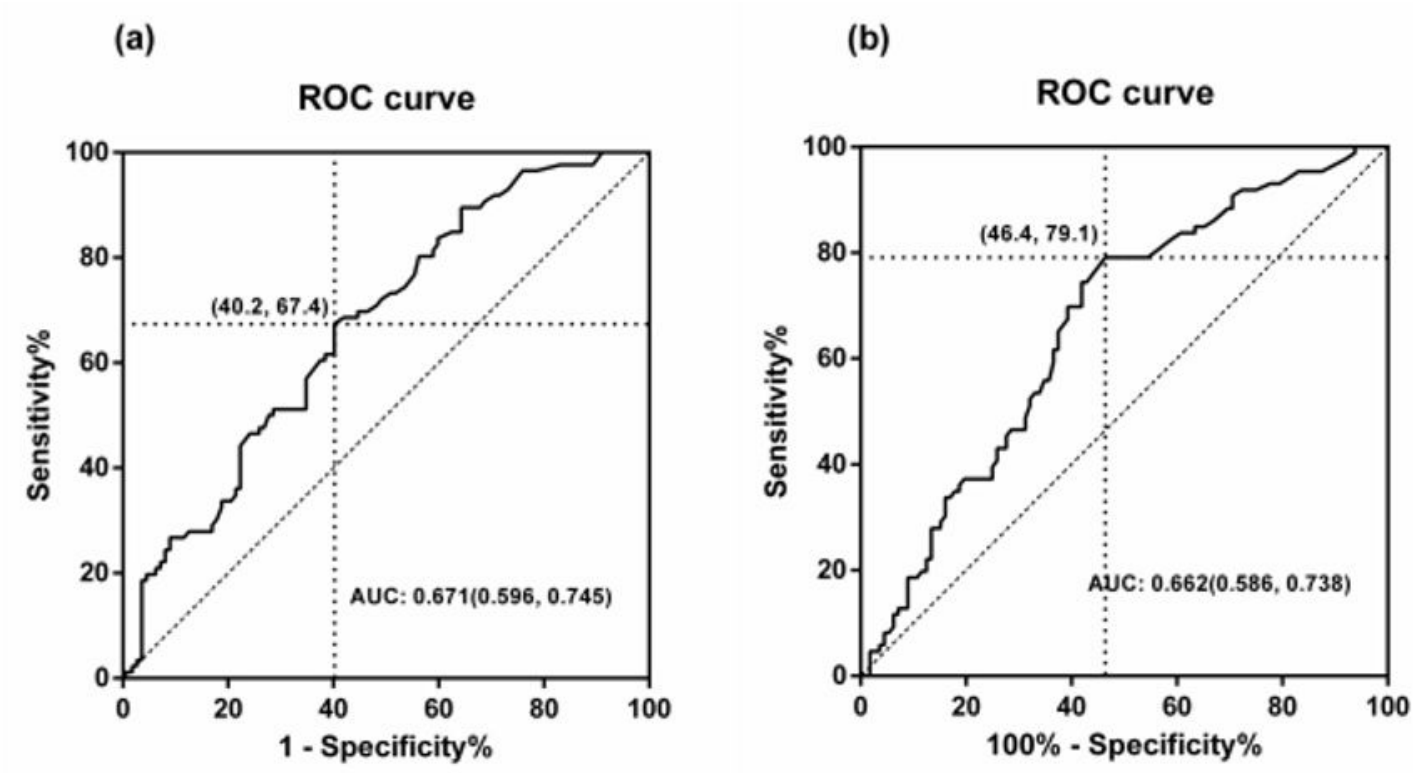

Figure 1

PASS cut-off points for the PASI and BSA scores. (a) The ROC curve analysis for the PASI threshold for PASS. A PASI score of 3.95 best differentiated psoriasis patients in PASS. (b) The ROC curve analysis for the BSA threshold for PASS. A BSA score of 2.85% best differentiated patients in PASS.