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Reliability and validity of the Chinese version of the Patient Health Questionnaire 9 (C-PHQ-9) in patients with psoriasis

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Reliability and validity of the Chinese version of the Patient Health

Questionnaire 9 (C-PHQ-9) in patients with psoriasis

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ABSTRACT

Objective: To evaluate the clinical reliability and validity of the Chinese version of the Patient Health Questionnaire 9 (C-PHQ-9) in psoriasis patients with depression.

Design: Cross-sectional study

Setting: Tertiary care center

Participants: Patients with psoriasis complicated with depression (n=148; mean age 43.37±17.46; female 31.19%).

Primary and secondary outcome measures: The primary outcome measures considered in this study were C-PHQ-9 and Hamilton Depression scale (HAMD). American Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM-V) was used as the gold standard for the diagnosis of depression. Reliability analysis was evaluated using Cronbach's α and test-retest reliability after 1 week and validity analysis was evaluated by criterion validity and structural validity. Receiver operating characteristic (ROC) analysis was used to detect the best demarcation score and diagnostic accuracy.

Results: Both C-PHQ-9 (39.19%) and HAMD (31.01%) had higher rates of detecting depression compared to DSM-V (20.27%). The mean completion time for C-PHQ-9 evaluation (2.02±0.84 minutes) was significantly less than that for HAMD (23.37±3.21 minutes, $P<0.001$). Cronbach's α coefficient for the C-PHQ-9 was 0.938. The correlation coefficients of the nine items with the total scale ranged from 0.540~ to 0.854, and the mean inter-item correlation coefficients ranged from 0.376 to 0.933. After a week, the retest coefficient was 0.955 ($P<0.01$). Principal component factor analysis showed that C-PHQ-9 identified a unifactorial structure. The best cutoff point was 9 points, sensitivity was 98.00%, and specificity was 90.80%. The area under the ROC curve was 0.979 (95% CI: 0.968 to 0.991).

Conclusion: C-PHQ-9 has good reliability and validity for patients with psoriasis. It can be used for the primary screening of patients with psoriasis and depression. This

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4 scale has obvious time and labor advantages over the Hamilton Depression Scale
5 (HAMD) and should be considered for use in clinical practice.
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8 *Key words:* C-PHQ-9; Reliability; Validity; Psoriasis; Depression
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STRENGTHS AND LIMITATIONS OF THIS STUDY

- The main strength of this study is that all psoriasis patients were assessed using the gold standard (DSM-V) tool for evaluating depression
- The C-PHQ-9 scale was also innovatively applied to patients with psoriasis
- Further, the time to complete C-PHQ-9 and HAMD was also assessed
- However, the study was limited by its small sample size
- The study was also limited by its cross-sectional and single-center design

INTRODUCTION

Psoriasis is a chronic inflammatory systemic disease that affects about 2% of the population.[1] Psoriasis is characterized by hyperproliferation of the epidermis resulting in thick, red, scaly lesions.[2] Itchiness, skin flaking, swelling, redness, pain and other manifestations frequently accompany the lesions, and the arthritic complications of the disease can cause pain and lead to loss of mobility and even disability.[3] A study revealed that depression is a common complication of psoriasis, with an incidence of about 22.1%.[1]

Currently, there are more than 10 kinds of assessment scales for clinical depression. Different studies have shown that different assessment scales have different detection rates for depression.[4] The most widely used is the Hamilton Depression Scale (HAMD), but owing to its complexity and need for professional input, it requires more labor and time. The Chinese version of the Patient Health Questionnaire 9 (C-PHQ-9) is a self-evaluation tool for the diagnosis and assessment of depression based on the major disorder of the Diagnostic and Statistical Manual of Mental Disorders (4th Edition) (DSM-IV).[5]

The treatment for psoriasis is usually difficult and often unsatisfactory. Psoriasis has a profound impact on the quality of life of patients, and patients often experience depression, anxiety, and even suicidal behavior. Moreover, disorders in psoriasis that are related to the patient's mental wellbeing are key factors leading to the recurrence of psoriasis. Therefore, clinicians should screen and detect patients with psoriasis early, and develop individualized psychosomatic treatment programs for patients with psoriasis to adapt to the medical model under the new situation. However, the diagnosis of depression in the dermatology clinic is difficult for non-professional psychiatrists. In particular, professional, complex, and time-consuming survey scales makes such diagnosis more difficult to achieve. Therefore, it is necessary to find an accurate and simple depression screening tool. Considering the above, this study aimed to evaluate the clinical reliability and validity of the Chinese version of the Patient Health Questionnaire 9 (C-PHQ-9) in patients with depression.

METHODS

Study Design

The study was conducted in accordance with the tenets of the Declaration of Helsinki. Written consent for the use of clinical data in aggregated form was obtained from all patients after they were informed about the study procedures. In this observational study, 148 patients with psoriasis complicated with depression were included from the outpatient and inpatient departments of the affiliated Hospital of Southwest Medical University from January to February 2018. The diagnosis of depression was made by a psychiatrist using the American Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM-V), which is considered the gold standard for assessing depression. The psychiatrist determined each patient's HAMD score. The PHQ-9 is a self-evaluation tool for the major disorder based on the criteria of the Diagnostic and Statistical Manual of Mental Disorders (4th Edition). Every patient with psoriasis and depression completed a questionnaire we created, which aimed to evaluate the C-PHQ-9 score, sociological data, and treatment satisfaction. The designated personnel received standardized training to follow specific instructions to guide the patients to complete the questionnaire and assessment. The C-PHQ-9 was carefully and completely filled out by the patient after reading the questionnaire. HAMD and DSM-V were assessed by two attending physicians. The psychiatrist completed the assessment and recorded the time it took to complete each questionnaire.

Measurements

The assessment range for C-PHQ-9 considers only the time period within the previous 2 weeks, with each symptom having a possible score of 0 to 3 points (0 = no, 1 = a few days, 2 = more than half of the days, 3 = almost every day). The total score of the scale is 27 points, with 0 to 4 points indicating the absence of depression, 5 to 9 points for mild depression, 10 to 14 points for moderate depression, and 15 to 27 points for severe depression.

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4 A 17-item version of HAMD was used in this study, with a total score of 0 to 7 points
5 indicative of depression, 8 to 17 points of mild depression, 18 to 24 points of
6 moderate depression, and >24 points of severe depression.
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10 As noted above, DSM-V was used as the gold standard for diagnosis of depression.
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12 **Statistics**

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15 This study was a cross-sectional study. The data were processed and analyzed using
16 SPSS version 20.0 (IBM, Armonk, NY). Quantitative data are presented as
17 mean±standard deviation, and count data are expressed with percentages. In order to
18 calculate the internal consistency of HAMD and C-PHQ-9, we used Cronbach's α . To
19 derive the optimal cutoff points for HAMD and C-PHQ-9, we performed receiver
20 operating characteristic (ROC) analysis. We compared the areas under the ROC
21 curves (AUCs) to determine the respective abilities of HAMD and C-PHQ-9 to
22 diagnose depression. In all tests, statistical significance was defined as a *P*-value of
23 <0.05.
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34 **Patient and Public Involvement**

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37 Patients with psoriasis complicated with depression were included from the outpatient
38 and inpatient departments of the Affiliated Hospital of Southwest Medical University
39 from January to February 2018. The survey was approved by the Ethics Committee of
40 the Affiliated Hospital of Southwest Medical University, and all subjects signed the
41 informed consent form. The sample size was determined by retrieving previous
42 studies.
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51 **RESULTS**

52 **Patient characteristics**

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57 A total of 150 questionnaires were distributed in this survey, and 148 valid
58 questionnaires were collected (response rate 98.67%). The study sample comprised 90
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male (60.81%) and 58 female (31.19%) patients, with a mean age of 43.37 ± 17.46 (range 18 to 85) years. The mean disease course was 9.63 ± 7.85 (range 0.5 to 43) years. Table 1 outlines the sociodemographic variables considered in the study and the rate of depression with respect to each of these variables.

Table 1. Patient characteristics

Variables	Psoriasis parents n	C-PHQ-9(+) n	Positive rate/%	χ^2 value	P-value
Gender				0.009	0.926
male	90	35	38.89		
female	58	23	39.66		
Age/years				0.032	0.858
≤60	126	49	33.56		
>60	22	9	40.91		
Disease duration /years				8.984	0.003
≤10	91	27	29.67		
>10	57	31	54.39		
Marital status				0.814	0.666
unmarried	44	15	34.09		

married	100	41	41.00		
divorced or widowed	4	2	50.00		
Cultural level				1.334	0.248
junior high school and below	91	39	42.86		
high school and above	57	19	33.33		
Place of residence				0.613	0.434
city	58	25	43.10		
rural	90	33	36.67		

The incidence of depression in patients with psoriasis

This study identified 30 patients (20.27%) who met the DSM-V criteria for the diagnosis of depression, and 118 patients (79.73%) without depression. There was no significant difference between the C-PHQ-9 (39.19%) and HAMD (31.09%) detection rates for depression ($\chi^2=2.14$, $P=0.15$) (Table 2).

Table 2. C-PHQ-9 and HAMD scale depression findings (n, %)

Scale	Non-	Mild	Moderate	Severe
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	depressed patients	depression	depression	depression
C-PHQ-9	90 (60.81)	37 (25.00)	15 (10.14)	6 (4.05)
HAMD	102 (68.91)	29 (19.59)	10 (6.76)	7 (4.73)

Trust level analysis

Homogeneity reliability

The internal consistency coefficient (Cronbach's α coefficient) of the C-PHQ-9 scale was 0.938. The correlation coefficient between each item and the total score of the scale ranged from 0.540 to 0.854, and the correlation coefficient between each item ranged from 0.376 to 0.933, all of which demonstrated a significant correlation ($P < 0.01$) (Table 3).

Table 3. Correlation between items in C-PHQ-9 and each item and total score (r)

Items	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9
Q1	1.000								
Q2	0.608*	1.000							
Q3	0.749*	0.650*	1.000						
Q4	0.661*	0.788*	0.561*	1.000					
Q5	0.702*	0.606*	0.589*	0.634*	1.000				
Q6	0.625*	0.508*	0.591*	0.567*	0.680*	1.000			

Q7	0.490*	0.390*	0.431*	0.509*	0.589*	0.803*	1.000		
Q8	0.501*	0.376*	0.438*	0.527*	0.573*	0.804*	0.858*	1.000	
Q9	0.499*	0.376*	0.436*	0.543*	0.589*	0.804*	0.868*	0.933*	1.000
Total score	0.840*	0.839*	0.839*	0.854*	0.761*	0.683*	0.573*	0.575*	0.540*

Note: Q1 refers to the first score, Q2 refers to the second score, etc.; *P <0.01 (two-sided test).

Test reliability

The initial score and the retested C-PHQ-9 total score after 1 week were analyzed, and the correlation coefficient was 0.955 ($P < 0.01$).

Validity analysis

Validity

The consistency analysis between C-PHQ-9 and HAMD showed a kappa coefficient of 0.779. The two were divided into positive correlations, and the correlation coefficient was 0.504 ($P < 0.01$).

Structural validity

Principal component analysis showed that the KMO value was 0.877, and the Bartley spherical test statistic was 31130.97 ($P < 0.05$), indicating that there are common factors among the items, which is suitable for factor analysis. The principal component factor analysis was a one-factor structure, the extracted eigenvalue was 6.20, the variance of the factor was 68.88% of the total, and the factor load matrix coefficients of all the entries was greater than 0.572 (0.572 to 0.950).

ROC curve

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4 A total of 148 subjects were evaluated using the DSM-V, including 30 patients with
5 depression and 118 patients without depression, and DSM-V was used this as the
6 standard for the ROC curve, with the maximum Youden index (sensitivity +
7 specificity = 1). The best cutoff point for C-PHQ-9 was 9 points, with a sensitivity of
8 98.00% and a specificity of 90.80%. The AUC of C-PHQ-9 was 0.979 (95% CI:
9 0.968 to 0.991) (Figure 1).
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19 **Comparison of the completion time of the two scales**

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21 In this study, 148 patients completed C- PHQ-9 in a total time of about 298.96
22 minutes, while HAMD lasted about 3459.60 minutes. Moreover, the mean completion
23 time for each C-PHQ-9 evaluation (2.02±0.84 minutes) was significantly less than
24 that for each HAMD (23.37±3.21 minutes), and the difference was statistically
25 significant ($t=-78.37$, $P<0.001$).
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34 **DISCUSSION**

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36 About 300 million people worldwide are affected by depression,[6] with different
37 prevalence rates in different countries, including about 8.1% in the US,[7] 8.7% in
38 Argentina,[8] 14% in Brazil,[9] 5.9% to 9.8% in Germany,[10] 5.5% in
39 Singapore,[11] and 5.9% to 13.2% in China.[12-13] Psoriasis is a common chronic
40 inflammatory skin disease that has a notable impact on the lives of patients. A study
41 that employed different survey populations and screening tools found that 9% to 55%
42 of patients with psoriasis have depression.[4] Depression reduces the treatment
43 compliance of patients with psoriasis and, therefore, exacerbates psoriasis. However,
44 currently, dermatologists are not very aware of depression, which results in
45 undiagnosed depression in some psoriasis patients; thus, affecting the impact of
46 psoriasis. Depression testing in patients with psoriasis is currently limited by three
47 factors: (1) the high variability of currently available questionnaires, (2) the
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4 absence/lack of questionnaires designed and validated for patients with skin disorders,
5 and (3) the dermatologist's limited use and non-familiarity with questionnaires.[14]
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7 Therefore, it is necessary to find an evaluation scale for patients with psoriasis and
8 depression, which is both specific and sensitive, and economical and time-saving.
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12 Screening for depression refers to the use of a depression screening questionnaire to
13 identify patients who may have depression but have not been diagnosed with the
14 condition. PHQ-9 has been recommended by DSM-V for investigating depression and
15 has been shown to have good reliability and validity in different populations,[15-17]
16 but there are no reports on its use in patients with skin disorders. In this study, 148
17 patients with psoriasis were investigated using the C-PHQ-9 scale. The rate of
18 depression in patients with psoriasis using C-PHQ-9 scale was 39.19%. This is
19 consistent with previous research results.[4] The rate of depression was significantly
20 higher in patients with a disease duration >10 years. This finding is consistent with
21 other research results and seems reasonable because of the longstanding psoriasis in
22 these patients. Specificity in this study was similar to that in previous studies and
23 across reference standards. Based on semi-structured interviews, the standard cutoff
24 score of 10 maximized combined sensitivity and specificity, which yielded values of
25 98.00% and 90.80%, respectively. The Kappa coefficient between the C-PHQ-9 and
26 HAMD scales was 0.779. The two scales were divided into positive correlations, and
27 the correlation coefficient was 0.504, which indicates good consistency. The detection
28 of depression was higher with C-PHQ-9 and HAMD than with DSM-V, which is
29 consistent with previous studies, indicating that both have good false positive rates.
30 The time to complete C-PHQ-9 was less than that taken to complete HAMD.
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34 The main strength of this study is that all psoriasis patients were assessed using the
35 gold standard for evaluating depression. DSM-V and the C-PHQ-9 scale was
36 innovatively applied to patients with psoriasis. Moreover, the time to complete
37 C-PHQ-9 and HAMD was also assessed. However, the study was limited by its small
38 sample size and by its cross-sectional and single-center design. In the future,
39 randomized controlled trials are needed to analyze factors related to psoriasis and to
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4 test the effect of C-PHQ-9 in patients with psoriasis and depression.
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8 9 **Conclusions**

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11 C-PHQ-9 has the advantages of fewer items, easier administration, better clarity, high
12 screening efficiency, and having 9 diagnostic criteria for depression in DSM-V.
13 PHQ-9 not only provides value for screening, it can also assess the severity of
14 depression, and the scale has obvious time and labor advantages over HAMD.
15 Because of its simplicity, high sensitivity, and high specificity, we believe C-PHQ-9
16 should be strongly considered for use in the clinical setting for screening psoriasis
17 patients with depression, with a recommended cutoff score of ≥ 9 .
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40 Contributor ship statement: Xin Ye was involved in the study design, study
41 coordination, data analysis, and manuscript writing. Xia Feng contributed to the data
42 analysis and manuscript writing. Hui-ling Shu and Bei Yu were involved in patient
43 recruitment coordination and Chang-qiang Li was involved in the study design and
44 critical revision of the manuscript.
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53 Data sharing statement: No additional data are available.
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FIGURE LEGEND

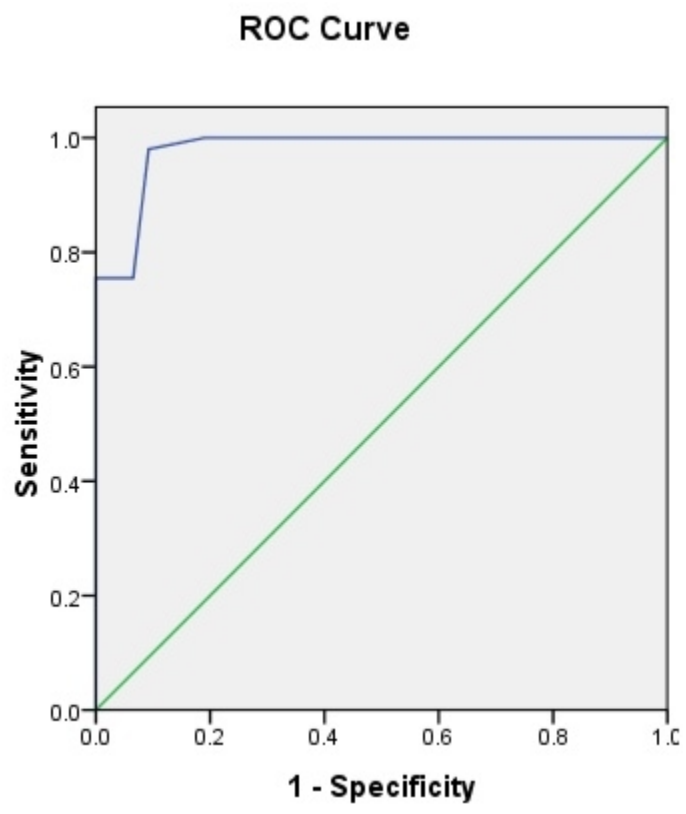
Figure 1. ROC curve of C-PHQ-9

Note: The blue line represents the ROC curve of C-PHQ-9, and the green line represents the diagnostic reference line.

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The blue line represents the ROC curve of C-PHQ-9, and the green line represents the diagnostic reference line.

125x145mm (72 x 72 DPI)

泸州市科技计划项目申报书

项目名称： （泸州-川医大）银屑病合并抑郁症患者的神经内分泌基础及共病机制研究（基础类）

项目领域： 医疗卫生

申报单位(盖章)： 四川医科大学

项目负责人： 黎昌强

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项目名称		(泸州-川医大) 银屑病合并抑郁症患者的神经内分泌基础及共病机制研究 (基础类)							
第一 承担 单位	单位名称	四川医科大学附属第一医院							
	通讯地址	四川省泸州市太平街 25 号				邮政编码	646000		
	单位负责人	廖斌				联系人	黎昌强		
	联系人电话	0830-3165059			联系人手机	13982768879			
	职工人数	1153		上级行政主管部门		四川省教育厅			
	单位性质	大专院校		单位经济类型		国有			
	企业特性								
	上年度企业 财务状况 (单位: 万元, 仅限企业填写)	资产总额				负债总额			
		固定资产原值				其中流动负债			
		固定资产净值				销售收入 总额			
流动资产				其中主营 业务收入					
纳税总额				所有者权益 总额					
净利润总额				其中实收资本					
项目 负责 人	姓名	黎昌强	性别	男	年龄	42	电话	13982768879	
	学历	研究生		学位		硕士			
	职称	副主任医师		职务		无			
	从事专业	皮肤性病学		所在单位		四川医科大学附属第一医院			
项目 协 作 单 位	序号	单位名称				在本项目中的分工			
	1	无				无			
	2								
	3								
	4								
	5								
	6								

项目组 人数	8	高级	4	中级	3	初级	1	其他	0
主要 研究 人员	姓名	性别	年龄	学历	职务(职称)	从事专业	所在单位		
	黎昌强	男	42	研究生	副主任医师	皮肤性病学	泸州医学院附属医院		
	廖勇梅	女	42	博士生	主治医师	皮肤性病学	泸州医学院附属医院		
	危薇	女	34	研究生	主治医师	神经病学	泸州医学院附属医院		
	徐灵玲	女	35	研究生	主治医师	检验科	泸州医学院附属医院		
	许颺	女	45	研究生	教授	皮肤性病学	泸州医学院附属医院		
	熊霞	女	52	研究生	教授	皮肤性病学	泸州医学院附属医院		
	张雪丽	女	35	研究生	主治医师	精神病学	泸州医学院附属医院		
	何鸿义	女	23	研究生	医师	皮肤性病学	泸州医学院		
项目简介	该研究拟通过经颅多普勒、脑电图检查及神经递质检测，并用不同疗法治疗银屑病合并抑郁症的患者，研究银屑病合并抑郁症患者的神经内分泌基础及共病机制，为皮肤科医师更好诊断及治疗银屑病合并抑郁症的患者提供指导。								
拥有专利情况	无								
拥有其它知识产权情况	无								
项目类别	应用基础								
预期成果与知识产权	论文著作(研究报告) 3 篇。无								
预期技术标准制定	国家标准 3 项,								
是否节能减排	不涉及								
是否涉及安全生产	否								
产学研联合	否								
经费预算	总投入 20.00 万元，其中申请市科技局拨款 20.00 万元								

一、立项的必要性及国内外研究现状、发展趋势和知识产权状况分析（不超过 4500 字，各栏中不得出现本项目的研究单位名称和项目组成员姓名）

银屑病（psoriasis）是一种常见的慢性复发性炎症性皮肤病，典型皮疹为丘疹，斑块和鳞屑。很多患者因为病情反复、瘙痒、外观受累、异味及外界的排斥而出现焦虑、抑郁，或反复出现自杀念头甚至自杀，严重影响患者及家庭的生活质量，属于典型的身心疾病。有人把它称为“不死的癌症”。

目前国内外很多学者研究显示银屑病患者中抑郁症比例高达 60-80%^{[1][2]}，但是银屑病的本身导致了抑郁还是与抑郁本身有共同的遗传背景至今尚不明确，大部分研究主要局限于流调或是简单的心理护理^{[3][4]}，甚至很多伴有重度抑郁或有自杀意念或自杀倾向的银屑病人也往往被忽视，或是发现了患者却不愿到精神科就诊，而皮肤科医师面对诸多的精神科用药（比如三环类抗抑郁药、单胺氧化酶抑制剂、选择性 5-HT 再摄取抑制剂、选择性 NE 再摄取抑制剂、选择性 NE 和 5-HT 双重摄取抑制剂等等）束手无策。

虽然有很多学者对抑郁症进行了大量的研究，包括经颅多普勒(TCD)、脑电图(EEG)^[5]、功能磁共振成像分析(fMRI)及脑神经递质^[6]的检测等，发现抑郁症可以通过影像或是外周血的检测客观反映。比如刘榴^[7]等研究表明随着抑郁程度的逐渐加重，双侧大脑 MCA、ACA 及 PCA 的血流速度逐渐加快，脑电图以轻度异常及边缘(界限)为主，并没有出现重度异常，随着抑郁程度的增强，患者脑电图的异常程度也在加重，主要表现为 α 节律慢化甚至消失， β 活动增多，出现 θ 波及 δ 波，这些表现有利于临床医生选择相应的抗抑郁药物，意义重大。只是没有关于银屑病合并抑郁的患者的研究，银屑病合并抑郁的患者抑郁问题往往被忽视，这部分患者没有得到合理的治疗，对身心造成严重影响，心情的抑郁也可能是这部分患者反复发作的主要原因。所以弄清楚如何快速客观的甄别银屑病是否合并抑郁症以及抑郁症的程度，对皮肤科医师对这类患者进行有效的心理及药物治疗非常必要。

而要做到这一点，靠单打独斗已经满足不了需要，整合医学应运而生，皮肤身心疾病需要有大量的学者对银屑病的社会-心理-生理医学模式的做进一步探索。对于银屑病合并抑郁症患者，如果能做到以下几点：

①明确银屑病合并抑郁症患者的 TCD、EEG 的表现，无损且准确、直观地

观察到患者脑功能活动的部位和范围以及与正常人的差异；

②了解银屑病合并抑郁症的患者血清单胺类神经递质的表达，并分析血清单胺类神经递质的含量是否与相应脑功能区的变化存在相应的联系；

③为皮肤科医师提供快速客观的甄别银屑病合并抑郁症的方法，也为皮肤科医师对这类患者进行有效的心理及药物治疗提供客观依据；

④探索银屑病合并抑郁症的共病机制，为进一步研究抑郁症导致银屑病加重与复发的神经免疫及神经内分泌机制奠定基础。

那将为临床探索出快速客观的甄别银屑病是否合并抑郁症以及抑郁症的程度方法，为皮肤科医师提供对这类患者进行有效的心理及药物治疗的依据。所以通过对银屑病合并中重度抑郁症患者的经颅多普勒、脑电图分析及血清单胺类神经递质的检测，探讨银屑病合并抑郁症患者的神经内分泌基础及共病机制意义重大，是非常必要的。

参考文献：

[1] Masoud Golpour,Seyed Hamzeh Hosseini. Depression and Anxiety Disorders among Patients with Psoriasis:A Hospital- Based Case-Control Study[J].Dermatology Research and Practice,2012,10:1-5.

[2] Devane CL, Chiao E, Franklin M. Anxiety disorders in the 21st century: status, challenges, opportunities, and comorbidity with depression [J]. AmJ Manag Care,2005, 11(12Suppl):S344-S353.

[3] 孟琳琳.综合康复治疗对抑郁症患者疗效及认知功能改善的对照研究[J].山东医学高等专科学校学报.2015,37(1):7-10.

[4] 郑益志,陈春风,贾丽莹.中医情志疗法对寻常型银屑病患者 HAMD, HAMA 水平及外周血单胺类神经递质的影响[J].浙江中医药大学学报,2013,37(5):506-509.

[5] Wangner G,Schultz CC,Koch K. Prefrontal cortical thickness in depressed patient with high-risk for suicidal behavior[J]. J Psychiatr Res.2012;46(11):1449-55.

[6] 池名,青雪梅,潘彦舒.120例抑郁症患者大脑多神经递质变化初探[J]. 2014, 39(8):1516-1523.

[7] 刘榴,郑洪波,张惠云等.经颅多普勒与脑电图在抑郁症诊断中的价值[J].现代中西医结合杂志,2013,22(36):4076-4077.

二、项目研究主要目标、主要内容、技术关键、技术路线和应用方案（不超过 3500 字，各栏中不得出现本项目的研究单位名称和项目组成员姓名）

第一部分 银屑病抑郁患者的 TCD、EEG 特征及神经递质的表达

1 研究对象

1.1 试验组（拟 60 例）：来自我院皮肤科住院病人。

1.1.1 纳入标准：

临床及病理确诊为银屑病，同时符合美国精神疾病诊断与统计手册第 4 版 (DSM-IV) 抑郁症的诊断标准：年龄 18-60 岁，性别不限，汉密尔顿抑郁量表 (HAMD) 评定：24 项 HAMD 总分 ≥ 18 分。C-PHQ-9 评定：总分 27 分，0~4 分无抑郁，5~9 分轻度抑郁，10~14 分中度抑郁，15~27 分重度抑郁。抑郁症诊断由主治医师以上精神科医师协助完成。

1.1.2 排除标准：

正在接受抑郁症药物治疗的患者；合并其他精神障碍者；药物酒精依赖者；神经系统变性疾病、脑外伤或脑血管病患者以及严重心、肝、肾功能不全、糖尿病等重大躯体疾病患者；近期有过严重感染或手术者；精神分裂症等所导致的抑郁发作；正在接受激素类药物治疗；怀孕、哺乳妇女及月经期就诊女性；符合诊断标准但不愿参与本项研究者。

1.2 对照组（拟 30 例）：同期、同年龄段在我院体检的健康体检者 30 例。

纳入组标准：无严重躯体疾病或药物依赖者；目前精神状况好，无精神障碍史；无精神病家族史。

保证试验组与对照组的性别、年龄有可比性。本研究经我院医学伦理委员会批，所有受试者知情并签署同意书。

2 研究方法

2.1 病例筛选方法：临床及病理确诊为银屑病，抑郁症诊断由主治医师以上精神科医师协助完成，按照美国精神疾病诊断与统计手册第 4 版 (DSM-IV) 抑郁症的诊断标准：年龄 18-60 岁，性别不限，汉密尔顿抑郁量表 (HAMD) 评定：24 项 HAMD 总分 ≥ 18 分入选。

2.2 TED 检查

采用[深圳市德力凯电子有限公司](#)生产的多功能血管超声仪 DTCD8100，（批准

文号：粤食药监械(准)字 2013 第 2230733 号), 由我院脑电图室资深专家按照厂家提供的说明书操作。

2.3 EEG 检查

采用[四川省智能电子实业公司](#)生产的数字化脑电监护分析仪 ZN5A00(批准文号：川食药监械(准)字 2010 第 2210104 号), 由我院脑电图室资深专家按照厂家提供的说明书操作。

2.4 单胺类神经递质检测

2.4.1 实验方法：采用酶联免疫法(ELISA)对去甲肾上腺素(NE)、肾上腺素(E)、以及多巴胺(DA)和儿茶酚胺进行检测。

2.4.2 主要仪器与试剂：主要仪器：高效液相库伦阵列电化学检测器(型号 5600ACA-1001, ESA 公司, 美国); 主要试剂：肾上腺素(E)、NE、多巴胺、儿茶酚胺的标准品、3, 4 二羟基苄胺(DHBA)、1-庚烷磺酸钠(HSA)、柠檬酸、柠檬酸三钠等(购自美国 Sigma 公司); 甲醇和乙腈(购自 TEDIA 公司); 其余试剂均为国产; 实验用水为超纯水。

2.4.3 标本采集：采血时间为每日 8:00-11:00 之间，女性处于非月经期抽取受试者肘静脉血 4ml 于促凝管中，血标本在室温静置 30min 后离心处理(5000r/min, 4℃离心 10min)，收集血清样品并置-80℃冰箱保存备用。

2.4.4 具体检测由两名我院资深检测人员按照厂家提供的说明书进行检测。

3 研究方案及技术路线

4 统计方法

数据采用 SPSS17.0 统计分析软件, 计量资料描述用($\pm s$), 组间比较采用独立样本 t 检验, 计数资料采用卡方检验, $P < 0.05$ 为差异有统计学意义。变量相关分析采用 Pearson 分析方法。

第二部分 不同疗法的疗效分析及银屑病与抑郁症共病机制探索

1 研究对象

来自实验第一部分的试验组, 按患者就诊先后分为观察组和对照组, 各 30 例, 为了观察疗效采用 PASI 评分对银屑病进行皮疹评分。

2 治疗方法

两组均采用阿维A 0.5mg/kg qd, 盐酸西替利嗪 10mg qn, 外用阿达帕林和卡泊三醇凝胶 bid, 并用凡士林护肤 bid, 1 月后, 阿维A 剂量减为 0.3mg/kg qd, 再用 1 月后减为阿维A 10mg qd 维持 1 月, 同时进行心理疏导, 观察组另外给予抗抑郁药物 (针对检测结果选用相应的抗抑郁药), 3 月后停药。

3 疗效评价

观察疗效, 采用汉密尔顿抑郁量表 (HAMD) 评估抑郁状况及 PASI 评分对银屑病进行皮疹评分, 评估治疗前后银屑病及抑郁症的改善情况, 同时对比两组治疗后的差异。

4 机制探索

对患者的 TCD、EEG 进行复查和单胺类神经递质的检测 (方法同第一部分)。对检测结果进行分析, 探索银屑病与抑郁症的共病机制。

5 研究方案及技术路线:

6 统计方法

数据采用 SPSS17.0 统计分析软件，计量资料描述用（ $\pm s$ ），组间比较采用独立样本 t 检验，计数资料采用卡方检验， $P < 0.05$ 为差异有统计学意义。变量相关分析采用 Pearson 分析方法。

三、项目的创新性（包括理论创新、应用创新、技术创新、国际、国内技术等方面的领先情况。不超过 2000 字，各栏中不得出现本项目的研究单位名称和项目组成员姓名）

本项目的先进性：

1 整合医学需求下皮肤身心疾病的研究，是对皮肤科常见但顽固且对患者身心、家庭影响巨大的疾病-银屑病的社会-心理-生理医学模式的进一步探索；

2 引入无创且经济的 TCD、EEG 检查及单胺类神经递质的检测来客观评价银屑病患者抑郁的程度，有望找到简单客观的评价银屑病与抑郁症共病的指标，用于临床诊断与治疗的指导；

3 采用 TCD、EEG 检查及单胺类神经递质的检测观察不同方法对银屑病和抑郁症共病的治疗效果及治疗前后 TCD、EEG 的变化，可以推断是银屑病的反复导致患者抑郁还是两者有共同的致病遗传基础，也可以为抑郁症在银屑病复发机制中的作用提供研究基础。

本项目的创新性：

1 该研究属于皮肤病-精神心理疾病共病的研究；

2 目前很多银屑病与抑郁共病的研究主要停留在流调，主观因素有一定影响，评价繁琐，缺乏简单客观的评价指标，本研究的目的是寻找这种无创且经济的评价方法；

3 到目前为止，还未检索到国内外有对银屑病抑郁症共病进行 TCD、EEG 检查及单胺类神经递质检测的报道，此方法属于创新研究；

4 该研究对银屑病和抑郁症共病的治疗方案选择有一定的帮助，对进一步研究银屑病和抑郁症共病的神经免疫及神经内分泌机制有一定的指导意义。

四、项目产学研结合情况（不超过 1000 字，各栏中不得出现本项目的研究单位名称和项目组成员姓名）

无。

五、项目应用前景、预期效益分析（应用前景应包括预期技术、经济指标等，预期效益应包括社会效益和经济效益。不超过 1500 字，各栏中不得出现本项目的研究单位名称和项目组成员姓名）

项目完成后 预期经济效益	年新增产值 0 万元	年新增利税 0 万元	年新增销售收入 0 万元	年新增创汇 0 万美元
项目完成后可实现年节约成本		0 万元		
增加就业（人）	促进农民增收（万元）		减少排污量（吨）	
0	0		0	

该课题着眼于目前普遍关注的身心疾病，应用整合医学的新理念，旨在从身心层面解决病人疾苦。对皮肤身心疾病进行研究，是对皮肤科常见但顽固且对患者身心、家庭影响巨大的疾病-银屑病的社会-心理-生理医学模式的进一步探索，拟通过对银屑病合并中重度抑郁症患者进行无创且经济的 TCD、EEG 检查及单胺类神经递质的检测来客观评价银屑病患者抑郁的程度，有望找到简单客观的评价银屑病与抑郁症共病的指标，用于临床诊断与治疗的指导；且推断是银屑病的反复导致患者抑郁还是两者有共同的致病遗传基础，也可以为抑郁症在银屑病复发机制中的作用提供研究基础。

该课题预期发表科研论文 3 篇，在国家级期刊发表，让更多的临床医生了解银屑病与抑郁症的共病特点及机制，掌握无创且经济的 TCD、EEG 检查及单胺类神经递质的检测等客观评价银屑病患者抑郁程度的方法，为临床诊治提供指导，是这部分病人得到更好的治疗，回归幸福，有很大的社会效益。

该课题还可以培养年轻医生 3 名，研究生 3 名，本科生 6 名以上。为医学事业培养后备人才。

六、已有研究基础和承担优势(包括与项目有关的前期研究状况、实验设备及设备条件、近三年主持或主研的科研成果;获奖及发表论文等情况。不超过 1500 字,各栏中不得出现本项目的研究单位名称和项目组成员姓名)

已有研究基础:

1 已经对我科 3 例银屑病合并抑郁症的患者进行了 TCD、EEG 检查及单胺类神经递质的检测,均有异常,课题的研究应该是不只是理论上有价值,实际也是有意义的。

2 现有研究条件:我院具备相应的实验条件和设备,课题组成员包括皮肤科、神经内科、精神科检验科的医师,由正高、副高、主治医师及主管技师等梯度组成,能保证试验的顺利完成。

近三年获得论文:

1	地塞米松雾化吸入治疗重症药疹口腔损害的临床观察	第一作者	2012 年 19 期	现代预防医学 (中文核心)
2	IgA-pANCA 与过敏性紫癜的关系	第一作者	2013 年 12 期	中国皮肤性病学杂志 (中文核心)
3	白芍总苷治疗嗜酸细胞增高性湿疹的疗效观察及安全性分析	第一作者	2014 年 2 期	现代预防医学 (中文核心)
4	泸州医学院学生性安全教育前后性安全知识认知情况的调查分析	第一作者	2014 年 8 期	中国校外教育
5	IgA、IgG 型中性粒细胞胞浆抗体在过敏性紫癜中的表达与意义	第一作者	2013 年 1 期	泸州医学院学报

近三年主持的科研:

1	心得安溶液湿热敷治疗婴幼儿皮肤血管瘤的临床研究	泸州医学院附属医院课题	2012. 1- 2014. 12	2	第一主研
2	普萘洛尔溶液湿热敷治疗皮肤血管瘤的临床及机制研究	泸州医学院课题	2013. 1- 2015. 12	1	第一主研
3	皮肤科 CPC+PBL 教学模式的构建与探索	泸州医学院教改课题	2011. 1- 2012. 12	0. 3	第一主研
4	模拟门诊在研究生皮肤性病学教学中的构建与探索	泸州医学院研究生院课题	2014. 1-201 5. 12	0. 5	第一主研

七、项目计划进度和预期目标（不超过 1000 字，各栏中不得出现本项目的研究单位名称和项目组成员姓名）（注：填写此栏请与申报书封面的“起止年限”的年和月都要保持一致，计划进度填写的跨度不要太大。）

2016 年 01 月 - 2016 年 06 月	完成病例筛选，并完成第一部分实验，并做好相关记录
2016 年 07 月 - 2016 年 12 月	对实验组进行第二部分研究，并按研究计划进行，并做好实验记录
2017 年 01 月 - 2017 年 06 月	第一部分资料整理，统计分析、论文写作及发表
2017 年 07 月 - 2018 年 06 月	第二部分资料整理，统计分析、论文写作及发表
2018 年 07 月 - 2018 年 12 月	结题

八、经费预算(单位: 万元人民币)

序号	预算科目名称	合计	财政科技经费	自筹经费	
1	一、经费支出	20.00	20.00		
2	(一)直接费用	17.00	17.00		
3	1、设备费				
4	(1)购置设备费				
5	(2)试制设备费				
6	(3)设备发行与租赁费				
7	2、材料费	10.00	10.00		
8	3、测试化验加工费				
9	4、燃料动力费				
10	5、差旅费	1.50	1.50		
11	6、会议费				
12	7、国际合作与交流费				
13	8、出版/文献/信息传播/知识产权事务费	1.50	1.50		
14	9、劳务费	4.00	4.00		
15	10、专家咨询费				
16	11、其他费用				
17	(二)间接费用	3.0	3.0		
18	其中: 绩效支出	0.3	0.3		
19	二、经费来源	20.00	20.00		
20	1、申请市级财政科技经费资助	20.00	20.00		
21	2、自筹经费来源				
22	(1)其他财政拨款				
23	(2)单位自有货币资金				
24	(3)其他资金				
		合计	第1年	第2年	第3年
财政科技经费 拨付进度 申请	金额	20.00	20.00		
	比例(%)	100	100		
自筹经费 投入	金额	0.00			
	比例(%)	0			

项目组 人员组 成情况	高端 科技 人才	科学院院士（） 工程院院士（） 享受国务院特殊津贴专家（） 长江学者奖励计划（） 国家“千人计划”（） 省“百人计划”（） 省优专家（） 省学术和技术带头人及其后备人选（1） 省杰出创新人才（）		
	高层次 人才	市拔尖人才（） 市学术和技术带头人及其后备人选（1） 酒城英才（） 市科技杰出贡献奖获奖人员（）		
	学历	博士后（） 博士研究生（1） 硕士研究生（7） 本科生（） 大专生（）		
	学位	博士（1） 硕士（7） 学士（）		
	职称	研究系列	高级（3） 中级（4） 初级（1）	
		工程系列	高级（） 中级（） 初级（）	
		教师系列	高级（） 中级（） 初级（）	
		其他系列	高级（） 中级（） 初级（）	
年龄	35岁以下（4） 36到45岁（2） 46到55岁（2） 56岁以上（）			
引进人 才类别	海外人才（） 省外人才（）			
引进人 才方式	调入（） 聘用（） 兼职（）			
项目研究 期间培养 人才计划	高端 人才	科学院院士（） 工程院院士（） 享受国务院特殊津贴专家（） 长江学者奖励计划（） 国家“千人计划”（） 省“百人计划”（） 省优专家（） 省学术和技术带头人及其后备人选（） 省杰出创新人才（）		
	高层次 人才	市拔尖人才（） 市学术和技术带头人及其后备人选（） 酒城英才（） 市科技杰出贡献奖获奖人员（）		
	职称 晋升	研究系列	高级（） 中级（）	
		工程系列	高级（） 中级（）	
		教师系列	高级（） 中级（3）	
		其他系列	高级（） 中级（）	
在读 人才	在读博士后（） 在读博士研究生（） 在读硕士研究生（3） 在读本科生（6）			
项目研究期间吸纳 大学生就业情况	学历	博士后（） 博士研究生（） 硕士研究生（1） 本科及大专（）		
	毕业时间	当年（1） 去年（） 前年（）		

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十、 审批情况
项目申报单位意见
<p style="text-align: right;">领导签字： （公章）</p> <p style="text-align: right;"> 年 月 日</p>
归口部门意见
<p style="text-align: right;">领导签字： （公章）</p> <p style="text-align: right;"> 年 月 日</p>

附件：3

序号	附件名称
1	汉密尔顿抑郁量表、PHQ-9 量表
2	PASI 评分
3	抑郁症的 DSM-IV 诊断标准

Hamilton 汉密尔顿抑郁量表(HAMD) (24 项)

HAMD 量表是临床上评定抑郁状态时最常用的量表。

五级评分项目：

(0) 为无 (1) 轻度 (2) 中度 (3) 重度 (4) 很重

三级评分项目：

(0) 为无 (1) 轻度~中度 (2) 重度

1. 抑郁情绪

- | 只在问到时才诉述；-----1
- | 在言语中自发地表达；-----2
- | 不用言语也可从表情、姿势、声音或欲哭中流露出这种情绪；----- 3
- | 病人的自发语言和非自发语言（表情、动作），几乎完全表现为这种情绪。----- 4

2. 有罪感

- | 责备自己，感到自己已连累他人；----- 1
- | 认为自己犯了罪，或反复思考以往的过失和错误；----- 2
- | 认为目前的疾病，是对自己错误的惩罚，或有罪恶妄想；----- 3
- | 罪恶妄想伴有指责或威胁性幻觉。----- 4

3. 自杀

- | 觉得活着没有意义；----- 1
- | 希望自己已经死去，或常想到与死有关的事；----- 2
- | 消极观念（自杀念头）；----- 3
- | 有严重自杀行为。----- 4

4. 入睡困难

- | 主诉有时有入睡困难，即上床后半小时仍不能入睡；----- 1
- | 主诉每晚均有入睡困难。----- 2

5. 睡眠不深

- | 睡眠浅多恶梦；----- 1
- | 半夜（晚上 12 点以前）曾醒来（不包括上厕所）。----- 2

6. 早醒

- | 有早醒，比平时早醒 1 小时，但能重新入睡；----- 1
- | 早醒后无法重新入睡。----- 2

7. 工作和兴趣

- | 提问时才诉述；----- 1

- 1
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4 | 自发地直接或间接表达对活动、工作或学习失去兴趣，
5 如感到没精打采，犹豫不决，不能坚持或需强迫自己去工作或活动； ----- 2
6 | 病室劳动或娱乐不满 3 小时； ----- 3
7 | 因目前的疾病而停止工作，住院患者不参加任何活动或者没有他人帮助便不能完成病室日常事务。 4
8
9 **8. 迟缓：**指思维和语言缓慢，注意力难以集中，主动性减退。
10 | 精神检查中发现轻度迟缓； ----- 1
11 | 精神检查中发现明显迟缓； ----- 2
12 | 精神检查进行困难； ----- 3
13 | 完全不能回答问题（木僵）。 ----- 4
14
15 **9. 激越**
16 | 检查时表现的有些心神不定； ----- 1
17 | 明显的心神不定或小动作多； ----- 2
18 | 不能静坐，检查中曾站立； ----- 3
19 | 搓手，咬手指，扯头发，咬嘴唇。 ----- 4
20
21 **10. 精神性焦虑**
22 | 问到时才诉述； ----- 1
23 | 自发地表达； ----- 2
24 | 表情和言谈流露明显忧虑； ----- 3
25 | 明显惊恐。 ----- 4
26
27 **11. 躯体性焦虑：**指焦虑的生理症状，包括口干、腹胀、腹泻、打呃、腹绞痛、心悸、头痛、过度换气和叹息、以及尿频和出汗等。
28 | 轻度； ----- 1
29 | 中度，有肯定的上述症状； ----- 2
30 | 重度，上述症状严重，影响生活或需加处理； ----- 3
31 | 严重影响生活和活动。 ----- 4
32
33 **12. 胃肠道症状**
34 | 食欲减退，但不需他人鼓励便自行进食； ----- 1
35 | 进食需他人催促或请求或需要应用泻药或助消化药。 ----- 2
36
37 **13. 全身症状**
38 | 四肢、背部或颈部沉重感，背痛，头痛，肌肉疼痛，全身乏力或疲倦； ----- 1
39 | 上述症状明显。 ----- 2
40
41 **14. 性症状：**指性欲减退、月经紊乱等。
42 | 轻度； ----- 1
43 | 重度。 ----- 2
44 | 不能肯定，或该项对被评者不适合。（不计入总分）
45
46 **15. 疑病**
47 | 对身体过分关注； ----- 1
48 | 反复考虑健康问题； ----- 2
49 | 有疑病妄想； ----- 3
50 | 伴幻觉的疑病妄想。 ----- 4
51
52 **16. 体重减轻**
53 | 一周内体重减轻 1 斤以上； ----- 1
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- 1
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3 | 一周内体重减轻 2 斤以上。----- 2
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6 **17. 自知力**
7 | 知道自己有病, 表现为忧郁; ----- 0
8 | 知道自己有病, 但归于伙食太差、环境问题、工作过忙、病毒感染或需要休息等。1
9 | 完全否认有病。----- 2
10
11 **18. 日夜变化 (如果症状在早晨或傍晚加重, 先指出哪一种, 然后按其变化程度评分)**
12 | 轻度变化; ----- 1
13 | 重度变化。----- 2
14
15 **19. 人格解体或现实解体: 指非真实感或虚无妄想。**
16 | 问及时才诉述; ----- 1
17 | 自发诉述; ----- 2
18 | 有虚无妄想; ----- 3
19 | 伴幻觉的虚无妄想。----- 4
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22 **20. 偏执症状**
23 | 有猜疑; ----- 1
24 | 有关系观念; ----- 2
25 | 有关系妄想或被害妄想; ----- 3
26 | 伴有幻觉的关系妄想或被害妄想。----- 4
27
28 **21. 强迫症状: 指强迫思维和强迫行为。**
29 | 问及时才诉述; ----- 1
30 | 自发诉述。----- 2
31
32
33 **22. 能力减退感**
34 | 仅于提问时方引出主观体验; ----- 1
35 | 病人主动表示能力减退感; ----- 2
36 | 需鼓励、指导和安慰才能完成病室日常事务或个人卫生; ----- 3
37 | 穿衣、梳洗、进食、铺床或个人卫生均需他人协助。----- 4
38
39
40 **23. 绝望感**
41 | 有时怀疑“情况是否会好转”, 但解释后能接受; ----- 1
42 | 持续感到“没有希望”, 但解释后能接受; ----- 2
43 | 对未来感到灰心、悲观和绝望, 解释后不能排除; ----- 3
44 | 自动反复诉述“我的病不会好了”或诸如此类的情况。----- 4
45
46
47 **24. 自卑感**
48 | 仅在询问时诉述有自卑感 (我不如他人); ----- 1
49 | 自动诉述有自卑感 (我不如他人); ----- 2
50 | 病人主动诉述: “我一无是处”或“低人一等”, 与评 2 分者只是程度的差别----- 3
51 | 自卑感达妄想的程度, 例如“我是废物”类似情况。----- 4
52
53

结果分析:

- 54 总分 < 8 分: 正常;
55 总分在 8~17 分: 可能有抑郁症;
56 总分在 18~24 分: 肯定有抑郁症;
57 总分 >24 分: 严重抑郁症
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PHQ-9 量表调查

根据下面 9 个问题回答，在符合您的选项对应分数上面打✓，其中“完全不会”为 0 分，“好几天”为 1 分，“一半以上的天数”为 2 分，“几乎每天”为 3 分。请将答案的相应评分进行总和。

序号	在过去的两周内，以下情况 困扰您有多频繁？	评分			
		0=完全 不会	1=好几天	2=一半以 上的天数	3=几乎 每天
1	做事时提不起劲或没有兴趣				
2	感到心情低落，沮丧或绝望				
3	入睡困难，睡不安稳或睡眠过多				
4	感觉疲倦或没有活力				
5	食欲不振或吃太多				
6	觉得自己很糟或觉得自己很失败，或让自己或家人失望				
7	对事物专注有困难，例如阅读报纸或看电视时				
8	动作或说话速度缓慢到别人已经察觉？或正好相反-烦躁或坐立不安、动来动去的情况更胜于平常				
9	有不如死掉或用某种方式伤害自己的念头				
总分： _____					

银屑病皮损面积和严重程度指数(PASI)

一、皮损面积评价：

将全身分为4个部分评价，每个部分先自身评分，然后4部分评分结合起来记入最后 PASI 评分。这四部分分别是：下肢（占人体40%皮肤）；躯干（包括：胃部、胸部、背部等）占30%；上肢（占20%）；头部（占10%）。皮损面积占全身体表面积的比例计算如下：

体表各部分占区域头/颈、上肢、躯干、下肢百分比参考图

在受累部分以“X”标记，大致画出皮损范围和并指出拍照部位(含体表各部占各区域头/颈、上肢、躯干、下肢百分比参考)

临床观察医生签名：_____

日期：_____

部位	受累部分占此部位体表面积百分比
01 头/颈	%
02 躯干（包括腹股沟及会阴）	%
03 上肢	%
04 下肢（包括臀部）	%

皮损面积	得分
0%	0
< 10%	1
10-29%	2
30-49%	3
50-69%	4
70-89%	5
90-100%	6

二、严重程度指数：

1、**红斑**：对身体各部位红斑的评分采用以下 5 分制。

严重程度	得分
无症状	0
轻度	1
中度	2
重度	3
极其严重	4

2、**浸润**：对身体各部位浸润的评分采用以下 5 分制。

严重程度	得分
无症状	0
轻度	1
中度	2
重度	3
极其严重	4

3、**脱屑**：对身体各部位脱屑的评分采用以下 5 分制。

严重程度	得分
无症状	0
轻度	1
中度	2
重度	3
极其严重	4

三、各部位 PASI 得分的计算公式是：

PASI（头部）=0.1（红斑+浸润+脱屑）× 皮损面积；

PASI（上肢）=0.2（红斑+浸润+脱屑）× 皮损面积；

PASI（躯干）=0.3（红斑+浸润+脱屑）× 皮损面积；

PASI（下肢）=0.4（红斑+浸润+脱屑）× 皮损面积；

PASI 总分=PASI（头部）+PASI（上肢）+PASI（上肢）+PASI（躯干）

抑郁症的 DSM-IV 诊断标准

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4 A、在连续两周的时间里，病人表现出下列九个症状中的五个以上。这些症状必须
5 是病人以前没有的、或者极轻的。并且至少包括症状（1）和（2）中的一
6 个。
7

8
9 1, 每天的大部分时间心情抑郁，或者是由病人自我报告例如，（感到伤心，心
10 理空空的），或者是通过旁人的观察（例如，暗暗流泪）注意：在儿童和青少年
11 中，可以表现为易激惹，而不是明显的心情抑郁。
12

13 2, 在每天大部分时间，对所有或者大多数平时感兴趣的活动失去了兴趣。或
14 者通过病人自我报告，或者通过旁人的观察。
15

16 3, 体重显著减少或增加（正常体重的 5%），食欲显著降低或增加。注意：
17 在儿童中，考虑缺乏正常的体重增加。
18

19 4, 每天失眠或者睡眠过多。
20

21 5, 每天精神运动亢进或减少（不止是自我主观感觉到的坐立不安或者不想
22 动，旁人都是可以观察得到）。
23

24 6, 每天感到疲劳，缺乏精力。
25

26 7, 每天感到自己没有价值，或者自罪自贬（可能出现妄想）。这不仅是普通
27 的自责，或只是对自己的抑郁感到丢脸。
28

29 8, 每天注意力和思考能力下降，做决定时犹豫不决（自我报告或者是旁人的观
30 察）。
31

32 9, 常常想到死（不只是惧怕死亡），或者常常有自杀的念头但没有具体的计
33 划，或者是有自杀的具体计划，甚至有自杀行为。
34

35 B、排除双向躁郁。（双向躁郁的诊断标准，请参见 躁郁症）
36

37 C、上述症状对病人的生活工作或其他重要方面造成严重影响。
38

39 D、上述症状不是由于药物的生理作用（例如，服药，吸毒，酗酒）或者躯体
40 疾病所引起（例如，甲状腺分泌降低）。
41

42 E、上述症状不能仅仅由丧失亲友来解释。（如果有丧失亲友的事件发生，那
43 么上述症状必须在事件发生后的两个月后仍存在，而且伴随着显著的生活工作
44 方面的功能缺损、病态的自罪自责，自杀观念，精神症状，或精神运动迟
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BMJ Open

Reliability and validity of the Chinese version of the Patient Health Questionnaire 9 (C-PHQ-9) in patients with psoriasis : a cross-sectional study

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4 **Reliability and validity of the Chinese version of the Patient Health**
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6 **Questionnaire 9 (C-PHQ-9) in patients with psoriasis: a**
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8 **cross-sectional study**
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ABSTRACT

Objective: To evaluate the clinical reliability and validity of the Chinese version of the Patient Health Questionnaire 9 (C-PHQ-9) in psoriasis patients with depression.

Design: Cross-sectional study

Setting: Tertiary care center

Participants: Patients with psoriasis who has not a diagnosis of depression before. (n=148; mean age 43.37±17.46 years; female 31.19%).

Primary and secondary outcome measures: The primary outcome measures considered in this study were C-PHQ-9 and Hamilton Depression scale (HAMD). The American Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM-V) was used as the gold standard for the diagnosis of depression. Cronbach's α and test-retest reliability after 1 week were evaluated using reliability analysis and criterion validity and structural validity were assessed using validity analysis. Receiver operating characteristic (ROC) analysis was performed to detect the best demarcation score and diagnostic accuracy.

Results: Compared with DSM-V(27.27%),both C-PHQ-9 (39.19%) and HAMD (31.01%) had higher rates of detecting depression . The mean completion time for C-PHQ-9 evaluation (2.02±0.84 minutes) was significantly less than that for HAMD (23.37±3.21 minutes, $P<0.001$). Cronbach's α coefficient for the C-PHQ-9 was 0.938. The correlation coefficients of the nine items with the total scale ranged from 0.540 to 0.854, and the mean inter-item correlation coefficients ranged from 0.376 to 0.933. After a week, the retest coefficient was 0.955 ($P<0.01$). Principal component factor analysis showed that C-PHQ-9 identified a unifactorial structure. The best cutoff point was 9 points, sensitivity was 98.00%, and specificity was 90.80%. The area under the ROC curve was 0.979 (95% confidence interval: 0.968 to 0.991).

Conclusion: C-PHQ-9 has good reliability and validity for patients with psoriasis. And can be used for the primary screening of patients with psoriasis and

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3 depression. This scale has obvious time and labor advantages over the HAMD and
4 should be considered for use in clinical practice.
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8 *Key words:* C-PHQ-9; Reliability; Validity; Psoriasis; Depression
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STRENGTHS AND LIMITATIONS OF THIS STUDY

- The main strength of this study is that all psoriasis patients were assessed using the gold standard (DSM-V) tool for evaluating depression.
- The C-PHQ-9 scale was also innovatively applied to patients with psoriasis.
- Furthermore, the time to complete C-PHQ-9 and HAMD was also assessed.
- However, the study was limited by its small sample size.
- The study was also limited by its cross-sectional and single-center design.

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INTRODUCTION

Psoriasis is a chronic inflammatory systemic disease with a strong genetic predisposition and autoimmune pathogenic traits that affects about 2% of the population.[1] Psoriasis is characterized by hyperproliferation of the epidermis resulting in thick, red, scaly lesions.[2] Itchiness, skin flaking, swelling, redness, pain and other manifestations frequently accompany the lesions, and the arthritic complications of the disease can cause pain and lead to loss of mobility and even disability.[3] Although the pathogenesis of psoriasis is not clear, it is currently believed to be mainly related to genetics, immunity, oxidative stress (OS), inflammatory response, and environment[4]. Psoriasis typically affects the skin, but may also affect the joints, and has been associated with a number of diseases. A study revealed that depression is a common complication of psoriasis, with an incidence of about 22.1%.[1] The impact of psoriasis on psychological and mental health is currently an important consideration due to the implications of the disease on social well-being and treatment. Patients with psoriasis have an increased prevalence of depression and anxiety and suicidal ideation. Interestingly, psoriasis treatment leads to improvement in anxiety symptoms.[5,6] Dantzer et al. Proposed a hypothesis of inflammatory cytokines for depression through a large number of animal experiments and clinical observations. Activated immune inflammatory pathways are now thought to participate in the development of depression. Some proinflammatory factors such as IL-1, TNF- α , and interferon- γ can cause psoriasis and also play an important role as neurotransmitters in depression.[7] The inflammatory response may be a common pathway for depression in patients with psoriasis.

Currently, there are more than 10 kinds of assessment scales for clinical depression. Different studies have shown that different assessment scales have different detection rates for depression.[8] The most widely used is the Hamilton Depression Scale (HAMD); However, owing to its complexity and need for professional input, it requires more labor and time. The Chinese version of the Patient Health Questionnaire 9 (C-PHQ-9) is a self-evaluation tool for the diagnosis and assessment of depression

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4 based on the major disorder of the Diagnostic and Statistical Manual of Mental
5 Disorders (4th Edition) (DSM-IV).[9]
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8 The treatment for psoriasis is usually difficult and often unsatisfactory. Psoriasis has a
9 profound impact on the quality of life of patients, and patients often experience
10 depression, anxiety, and even suicidal behavior. These adverse emotions can further
11 aggravate the condition of patients with psoriasis through the nervous-endocrine
12 system and the nervous-immune system, forming a vicious circle. The
13 "neurotransmitter hypothesis" suggests that neurotransmitters such as norepinephrine
14 (NE) and dopamine (DA) are abnormally expressed in patients with depression. These
15 neurotransmitters are important components of the neuro-endocrine-immunomodulatory
16 -ry system, which can regulate the phagocytosis and proliferation activity of
17 lymphocytes and macrophages, and may promote the occurrence and development of
18 psoriasis. Therefore, clinicians should screen and detect patients with psoriasis early
19 and develop individualized psychosomatic treatment programs for patients with
20 psoriasis to adapt to the medical model under the new situation. However, the
21 diagnosis of depression in the dermatology clinic is difficult for health care
22 practitioners who are not qualified psychiatrists. In particular, professional, complex,
23 and time-consuming survey scales makes such diagnoses more difficult to achieve.
24 Therefore, it is necessary to identify an accurate and simple depression screening tool.
25 Considering the above, this study aimed to evaluate the clinical reliability and validity
26 of the Chinese version of the Patient Health Questionnaire 9 (C-PHQ-9) in screening
27 patients with psoriasis for depression.
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METHODS

Study Design

The study was conducted in accordance with the tenets of the Declaration of Helsinki. Written consent for the use of clinical data in aggregated form was obtained from all patients after they were informed about the study procedures. In this observational study, 148 patients with psoriasis were included from the outpatient and inpatient departments of The Affiliated Hospital of Southwest Medical University from January to February 2018. The diagnosis of depression was made by a psychiatrist using the American Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM-V), which is considered the gold standard for assessing depression. The psychiatrist determined each patient's HAMD score. The PHQ-9 is a self-evaluation tool for the major disorder based on the criteria of the Diagnostic and Statistical Manual of Mental Disorders (4th Edition). Every patient from the sample group who had an additional previous diagnosis of depression completed a questionnaire we created, which aimed to evaluate the C-PHQ-9 score, sociological data, and treatment satisfaction. The designated personnel received standardized training to follow specific instructions to guide the patients to complete the questionnaire and assessment. The C-PHQ-9 was carefully and completely filled out by each patient after reading the questionnaire. HAMD and DSM-V were assessed by two attending physicians. The psychiatrist completed the assessment and recorded the time it took to complete each questionnaire.

Measurements

The assessment range for C-PHQ-9 considers only the time period within the previous 2 weeks, with each symptom having a possible score of 0 to 3 points (0 = no, 1 = a few days, 2 = more than half of the days, 3 = almost every day). The total score of the scale is 27 points, with 0 to 4 points indicating the absence of depression, 5 to 9 points for mild depression, 10 to 14 points for moderate depression, and 15 to 27 points for severe depression.

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4 A 17-item version of HAMD was used in this study, with a total score of 0 to 7 points
5 indicative of no depression, 8 to 17 points of mild depression, 18 to 24 points of
6 moderate depression, and >24 points of severe depression.
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10 As noted above, DSM-V was used as the gold standard for the diagnosis of
11 depression. The above questionnaires were collected by the same trained physician to
12 avoid selection bias.
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15 16 **Statistical analysis**

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19 In this cross-sectional study, data were processed and analyzed using SPSS version
20 20.0 (IBM, Armonk, NY). Listwise deletions were carried out to manage missing
21 values. Subgroup analysis was used to control confounding factors. Quantitative data
22 are presented as mean±standard deviation, and count data are expressed with
23 percentages. To calculate the internal consistency of HAMD and C-PHQ-9, we used
24 Cronbach's α . To derive the optimal cutoff points for HAMD and C-PHQ-9, we
25 performed receiver operating characteristic (ROC) analysis. We compared the areas
26 under the ROC curves (AUCs) to determine the respective abilities of HAMD and
27 C-PHQ-9 to diagnose depression. In all tests, statistical significance was defined as a
28 *P*-value of <0.05.
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39 **Patient and Public Involvement**

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42 Patients with psoriasis were included from the outpatient and inpatient departments of
43 the Affiliated Hospital of Southwest Medical University from January to February
44 2018. The survey was approved by the Ethics Committee of the Affiliated Hospital of
45 Southwest Medical University, and all subjects signed the informed consent form.
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49 The sample size was determined by retrieving previous studies.
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RESULTS

Patient characteristics

A total of 150 questionnaires were distributed in this survey, and 148 valid questionnaires were collected (response rate 98.67%). Each patient met the diagnostic criteria for psoriasis, and there were no other confounding factors such as systemic diseases and mental illness with a clear diagnosis. The study sample comprised 90 male (60.81%) and 58 female (31.19%) patients, with a mean age of 43.37 ± 17.46 (range 18 to 85) years. The mean disease course was 9.63 ± 7.85 (range 0.5 to 43) years. Table 1 outlines the sociodemographic variables considered in the study and the rate of depression with respect to each of these variables.

Table 1. Patient characteristics

Variables	Psoriasis patients n	C-PHQ-9(+) n	Positive rate/%	χ^2 value	P-value
Gender				0.009	0.926
Male	90	35	38.89		
Female	58	23	39.66		
Age/years				0.032	0.858
≤60	126	49	33.56		
>60	22	9	40.91		
Disease duration /years				8.984	0.003
≤10	91	27	29.67		

>10	57	31	54.39		
Marital status				0.814	0.666
Unmarried	44	15	34.09		
Married	100	41	41.00		
Divorced or widowed	4	2	50.00		
Cultural level				1.334	0.248
Junior high school and below	91	39	42.86		
High school and above	57	19	33.33		
Place of residence				0.613	0.434
City	58	25	43.10		
Rural	90	33	36.67		

Sub-analyses with men and women

To help identify particular populations in which the C-PHQ-9 is particularly useful by sub-analyses with men and women and based on disease duration. The results in table 2 and table 3 showed no statistically significant difference in the incidence of depression between men and women with the same disease duration ($P > 0.05$).

Table 2. Depression rate between men and women when the disease duration ≤ 10 years

Disease duration ≤ 10 years				
	Psoriasis patients	C-PHQ-9(+) n	χ^2 value	P-value
Male	57	17	0.002	0.967
Female	34	10		

Table 3. Depression rate between men and women when the disease duration > 10 years

Disease duration > 10 years				
	Psoriasis patients	C-PHQ-9(+) n	χ^2 value	P-value
Male	33	18	0.001	0.977
Female	24	13		

Incidence of depression in patients with psoriasis

This study identified 30 patients (20.27%) who met the DSM-V criteria for the diagnosis of depression, and 118 patients (79.73%) without depression. There was no

significant difference between the C-PHQ-9 (39.19%) and HAMD (31.09%) detection rates for depression ($\chi^2=2.14$, $P=0.15$) (Table 4).

Table 4. C-PHQ-9 and HAMD scale depression findings (n, %)

Scale	Non-depressed patients	Mild depression	Moderate depression	Severe depression
C-PHQ-9	90 (60.81)	37 (25.00)	15 (10.14)	6 (4.05)
HAMD	102 (68.91)	29 (19.59)	10 (6.76)	7 (4.73)

Trust level analysis

Homogeneity reliability

The internal consistency coefficient (Cronbach's α coefficient) of the C-PHQ-9 scale was 0.938. The correlation coefficient between each item and the total score of the scale ranged from 0.540 to 0.854, and the correlation coefficient between each item ranged from 0.376 to 0.933, all of which demonstrated a significant correlation ($P<0.01$) (Table 5).

Table 5. Correlation between items in C-PHQ-9 and each item and total score (r)

Items	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9
Q1	1.000								
Q2	0.608*	1.000							
Q3	0.749*	0.650*	1.000						
Q4	0.661*	0.788*	0.561*	1.000					
Q5	0.702*	0.606*	0.589*	0.634*	1.000				

Q6	0.625*	0.508*	0.591*	0.567*	0.680*	1.000			
Q7	0.490*	0.390*	0.431*	0.509*	0.589*	0.803*	1.000		
Q8	0.501*	0.376*	0.438*	0.527*	0.573*	0.804*	0.858*	1.000	
Q9	0.499*	0.376*	0.436*	0.543*	0.589*	0.804*	0.868*	0.933*	1.000
Total score	0.840*	0.839*	0.839*	0.854*	0.761*	0.683*	0.573*	0.575*	0.540*

Note: Q1 refers to the first score, Q2 refers to the second score, etc.; *P <0.01 (two-sided test).

Test reliability

The initial score and the retested C-PHQ-9 total score after 1 week were analyzed, and the correlation coefficient was 0.955 ($P < 0.01$).

Validity analysis

Validity

The consistency analysis between C-PHQ-9 and HAMD showed a kappa coefficient of 0.779. The two were divided into positive correlations, and the correlation coefficient was 0.504 ($P < 0.01$).

Structural validity

Principal component analysis showed that the KMO value was 0.877, and the Bartley spherical test statistic was 31130.97 ($P < 0.05$), indicating that there are common factors among the items, which is suitable for factor analysis. The principal component factor analysis was a one-factor structure, the extracted eigenvalue was 6.20, the variance of the factor was 68.88% of the total, and the factor load matrix coefficients of all the entries was greater than 0.572 (0.572 to 0.950).

ROC curve

A total of 148 subjects were evaluated using the DSM-V, including 30 patients with depression and 118 patients without depression, and DSM-V was used this as the standard for the ROC curve, with the maximum Youden index (sensitivity + specificity = 1). The best cutoff point for C-PHQ-9 was 9 points, with a sensitivity of 98.00% and a specificity of 90.80%. The AUC of C-PHQ-9 was 0.979 (95% confidence interval: 0.968 to 0.991) (Figure 1).

Comparison of the completion time of the two scales

In this study, the mean completion time for each C-PHQ-9 evaluation (2.02 ± 0.84 minutes) was significantly less than that for each HAMD (23.37 ± 3.21 minutes), and the difference was statistically significant ($t = -78.37$, $P < 0.001$).

DISCUSSION

About 300 million people worldwide are affected by depression,[10] with different prevalence rates in different countries, including about 8.1% in the US,[11] 8.7% in Argentina,[12] 14% in Brazil,[10] 5.9% to 9.8% in Germany,[13] 5.5% in Singapore,[14] and 5.9% to 13.2% in China.[15-16] Psoriasis is a common chronic inflammatory skin disease that has a notable impact on the lives of patients. A study that employed different survey populations and screening tools found that 9% to 55% of patients with psoriasis have depression.[8] However, currently, dermatologists are not very aware of depression, which results in undiagnosed depression in some psoriasis patients; thus, affecting the impact of psoriasis. Depression testing in patients with psoriasis is currently limited by three factors: (1) the high variability of currently available questionnaires, (2) the absence/lack of questionnaires designed and validated for patients with psoriasis disorders, and (3) the dermatologist's limited use and non-familiarity with questionnaires.[17] Therefore, it is necessary to find an evaluation scale for patients with psoriasis and depression, which is both specific and sensitive, and economical and time-saving.

Screening for depression refers to the use of a depression screening questionnaire to identify patients who may have depression but have not been diagnosed with the condition. PHQ-9 has been recommended by DSM-V for investigating depression and has been shown to have good reliability and validity in different populations,[18-20] but there are no reports on its use in patients with psoriasis disorders. In this study, 148 patients with psoriasis were investigated using the C-PHQ-9 scale. The rate of depression in patients with psoriasis using C-PHQ-9 scale was 39.19%. It is consistent with previous research results.[8] But after controlling the disease duration, there is no difference in the prevalence of depression between men and women. In future work, we will focus on whether C-PHQ-9 has a specific population that is particularly useful. The rate of depression was significantly higher in patients with a disease duration >10 years. This finding is consistent with other research results and seems

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4 reasonable because of the longstanding adverse effects of psoriasis in these patients.
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6 Specificity in this study was similar to that in previous studies and across reference
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8 standards. Based on semi-structured interviews, the standard cutoff score of 9
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10 maximized combined sensitivity and specificity, which yielded values of 98.00% and
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12 90.80%, respectively. In this study, we hoped to find a simpler, more convenient and
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14 efficient scale for dermatologists to evaluate the psychological state of patients with
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16 psoriasis in clinical work, and to timely identify patients with depression, and the
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18 results show the best truncation. The cutoff point is 9, the sensitivity and specificity
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20 can reach 98% and 90.8%, which is slightly different from previous studies.
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22 [21]Martin et al. found the best cutoff score is 10 , and this part of patients is the part
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24 of patients who need psychological intervention by psychologists. Our results can
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26 screen out some patients with early depression, and can take early psychological
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28 intervention to avoid serious consequences. The Kappa coefficient between the
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30 C-PHQ-9 and HAMD scales was 0.779. The two scales were divided into positive
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32 correlations, and the correlation coefficient was 0.504, which indicates good
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34 consistency. The detection of depression was higher with C-PHQ-9 and HAMD than
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36 with DSM-V, which is consistent with previous studies, indicating that both have
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38 good false-positive rates. The time to complete C-PHQ-9 was less than that taken to
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40 complete HAMD.

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42 The main strength of this study is that all psoriasis patients were assessed using the
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44 gold standard for evaluating depression. DSM-V and the C-PHQ-9 scale were
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46 innovatively applied to patients with psoriasis. Moreover, the time to complete
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48 C-PHQ-9 and HAMD was also assessed. However, the study was limited by its small
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50 sample size and its cross-sectional and single-center design. In the future, randomized
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52 controlled trials are needed to analyze factors related to psoriasis and assess the effect
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54 of C-PHQ-9 in patients with psoriasis and depression.
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CONCLUSIONS

C-PHQ-9 has the advantages of fewer items, easier administration, better clarity, high screening efficiency, and having 9 diagnostic criteria for depression in DSM-V. PHQ-9 not only provides value for screening but can also assess the severity of depression, and the scale has obvious time and labor advantages over HAMD. Because of its simplicity, high sensitivity, and high specificity, we believe C-PHQ-9 should be strongly considered for use in the clinical setting for screening psoriasis patients with depression, with a recommended cutoff score of ≥ 9 .

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Competing interests: None declared.

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Data sharing statement: No additional data are available.

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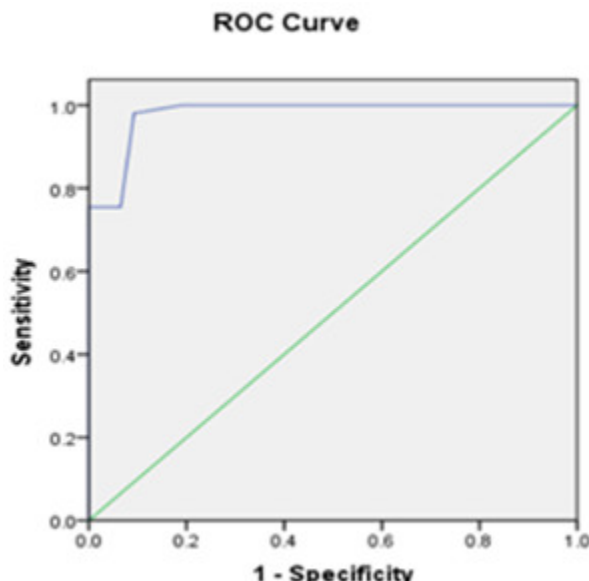
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13 **FIGURE LEGEND**

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16 Figure 1. ROC curve of C-PHQ-9

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18 Note: The blue line represents the ROC curve of C-PHQ-9, and the green line
19 represents the diagnostic reference line.
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The blue line represents the ROC curve of C-PHQ-9, and the green line represents the diagnostic reference line.

105x105mm (72 x 72 DPI)

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation
Title and abstract	1/2-3	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	5-6	Explain the scientific background and rationale for the investigation being reported
Objectives	6	State specific objectives, including any prespecified hypotheses
Methods		
Study design	7	Present key elements of study design early in the paper
Setting	7	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	7	(a) Give the eligibility criteria, and the sources and methods of selection of participants
Variables	7/8	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	8*	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	8	Describe any efforts to address potential sources of bias
Study size	7	Explain how the study size was arrived at
Quantitative variables	8	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	8	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses
Results		
Participants	9*	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	9*	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest
Outcome data	9*	Report numbers of outcome events or summary measures
Main results	12	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included (b) Report category boundaries when continuous variables were categorized (c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period
Other analyses	14	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses

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Discussion		
Key results	14	Summarise key results with reference to study objectives
Limitations	15	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	16	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	16	Discuss the generalisability (external validity) of the study results

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

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Reliability and validity of the Chinese version of the Patient Health Questionnaire 9 (C-PHQ-9) in patients with psoriasis : a cross-sectional study

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Keywords:	C-PHQ-9, Reliability, Validity, Psoriasis < DERMATOLOGY, Depression

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4 **Reliability and validity of the Chinese version of the Patient Health**
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6 **Questionnaire 9 (C-PHQ-9) in patients with psoriasis: a**
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12 Xin Ye^{1*}, Hui-ling Shu^{1*}, Xia Feng¹, Deng-mei Xia¹, Zheng-qun Wang¹,
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ABSTRACT

Objective: To evaluate the clinical reliability and validity of the Chinese version of the Patient Health Questionnaire 9 (C-PHQ-9) in psoriasis patients with depression.

Design: Cross-sectional study

Setting: Tertiary care center

Participants: Patients with psoriasis who has not a diagnosis of depression before. (n=148; mean age 43.37±17.46 years; female 31.19%).

Primary and secondary outcome measures: The primary outcome measures considered in this study were C-PHQ-9 and Hamilton Depression scale (HAMD). The American Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM-V) was used as the gold standard for the diagnosis of depression. Cronbach's α and test-retest reliability after 1 week were evaluated using reliability analysis and criterion validity and structural validity were assessed using validity analysis. Receiver operating characteristic (ROC) analysis was performed to detect the best demarcation score and diagnostic accuracy.

Results: Compared with DSM-V(27.27%),both C-PHQ-9 (39.19%) and HAMD (31.01%) had higher rates of detecting depression . The mean completion time for C-PHQ-9 evaluation (2.02±0.84 minutes) was significantly less than that for HAMD (23.37±3.21 minutes, $P<0.001$). Cronbach's α coefficient for the C-PHQ-9 was 0.938. The correlation coefficients of the nine items with the total scale ranged from 0.540 to 0.854, and the mean inter-item correlation coefficients ranged from 0.376 to 0.933. After a week, the retest coefficient was 0.955 ($P<0.01$). Principal component factor analysis showed that C-PHQ-9 identified a unifactorial structure. The best cutoff point was 9 points, sensitivity was 98.00%, and specificity was 90.80%. The area under the ROC curve was 0.979 (95% confidence interval: 0.968 to 0.991).

Conclusion: C-PHQ-9 has good reliability and validity for patients with psoriasis. And can be used for the primary screening of patients with psoriasis and

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depression. This scale has obvious time and labor advantages over the HAMD and should be considered for use in clinical practice.

Key words: C-PHQ-9; Reliability; Validity; Psoriasis; Depression

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STRENGTHS AND LIMITATIONS OF THIS STUDY

- The main strength of this study is that all psoriasis patients were assessed using the gold standard (DSM-V) tool for evaluating depression.
- The C-PHQ-9 scale was also innovatively applied to patients with psoriasis.
- Furthermore, the time to complete C-PHQ-9 and HAMD was also assessed.
- However, the study was limited by its small sample size.
- The study was also limited by its cross-sectional and single-center design.

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INTRODUCTION

Psoriasis is a chronic inflammatory systemic disease with a strong genetic predisposition and autoimmune pathogenic traits that affects about 2% of the population.[1] Psoriasis is characterized by hyperproliferation of the epidermis resulting in thick, red, scaly lesions.[2] Itchiness, skin flaking, swelling, redness, pain and other manifestations frequently accompany the lesions, and the arthritic complications of the disease can cause pain and lead to loss of mobility and even disability.[3] Although the pathogenesis of psoriasis is not clear, it is currently believed to be mainly related to genetics, immunity, oxidative stress (OS), inflammatory response, and environment[4]. Psoriasis typically affects the skin, but may also affect the joints, and has been associated with a number of diseases. A study revealed that depression is a common complication of psoriasis, with an incidence of about 22.1%.[1] The impact of psoriasis on psychological and mental health is currently an important consideration due to the implications of the disease on social well-being and treatment. Patients with psoriasis have an increased prevalence of depression and anxiety and suicidal ideation. Interestingly, psoriasis treatment leads to improvement in anxiety symptoms.[5,6] Dantzer et al. Proposed a hypothesis of inflammatory cytokines for depression through a large number of animal experiments and clinical observations. Activated immune inflammatory pathways are now thought to participate in the development of depression. Some proinflammatory factors such as IL-1, TNF- α , and interferon- γ can cause psoriasis and also play an important role as neurotransmitters in depression.[7] The inflammatory response may be a common pathway for depression in patients with psoriasis.

Currently, there are more than 10 kinds of assessment scales for clinical depression. Different studies have shown that different assessment scales have different detection rates for depression.[8] The most widely used is the Hamilton Depression Scale (HAMD); However, owing to its complexity and need for professional input, it requires more labor and time. The Chinese version of the Patient Health Questionnaire 9 (C-PHQ-9) is a self-evaluation tool for the diagnosis and assessment of depression

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4 based on the major disorder of the Diagnostic and Statistical Manual of Mental
5 Disorders (4th Edition) (DSM-IV).[9]
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8 The treatment for psoriasis is usually difficult and often unsatisfactory. Psoriasis has a
9 profound impact on the quality of life of patients, and patients often experience
10 depression, anxiety, and even suicidal behavior. These adverse emotions can further
11 aggravate the condition of patients with psoriasis through the nervous-endocrine
12 system and the nervous-immune system, forming a vicious circle. The
13 "neurotransmitter hypothesis" suggests that neurotransmitters such as norepinephrine
14 (NE) and dopamine (DA) are abnormally expressed in patients with depression. These
15 neurotransmitters are important components of the neuro-endocrine-immunomodulato
16 -ry system, which can regulate the phagocytosis and proliferation activity of
17 lymphocytes and macrophages, and may promote the occurrence and development of
18 psoriasis. Therefore, clinicians should screen and detect patients with psoriasis early
19 and develop individualized psychosomatic treatment programs for patients with
20 psoriasis to adapt to the medical model under the new situation. However, the
21 diagnosis of depression in the dermatology clinic is difficult for health care
22 practitioners who are not qualified psychiatrists. In particular, professional, complex,
23 and time-consuming survey scales makes such diagnoses more difficult to achieve.
24 Therefore, it is necessary to identify an accurate and simple depression screening tool.
25 Considering the above, this study aimed to evaluate the clinical reliability and validity
26 of the Chinese version of the Patient Health Questionnaire 9 (C-PHQ-9) in screening
27 patients with psoriasis for depression.
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METHODS

Study Design

This study is a cross-sectional study. The study was conducted in accordance with the tenets of the Declaration of Helsinki. Written consent for the use of clinical data in aggregated form was obtained from all patients after they were informed about the study procedures. In this observational study, 148 patients with psoriasis were included from the outpatient and inpatient departments of The Affiliated Hospital of Southwest Medical University from January to February 2018. The diagnosis of depression was made by a psychiatrist using the American Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM-V), which is considered the gold standard for assessing depression. The psychiatrist determined each patient's HAMD score. The PHQ-9 is a self-evaluation tool for the major disorder based on the criteria of the Diagnostic and Statistical Manual of Mental Disorders (4th Edition). Every patient from the sample group who had an additional previous diagnosis of depression completed a questionnaire we created, which aimed to evaluate the C-PHQ-9 score, sociological data, and treatment satisfaction. The designated personnel received standardized training to follow specific instructions to guide the patients to complete the questionnaire and assessment. The C-PHQ-9 was carefully and completely filled out by each patient after reading the questionnaire. HAMD and DSM-V were assessed by two attending physicians. The psychiatrist completed the assessment and recorded the time it took to complete each questionnaire.

Measurements

The assessment range for C-PHQ-9 considers only the time period within the previous 2 weeks, with each symptom having a possible score of 0 to 3 points (0 = no, 1 = a few days, 2 = more than half of the days, 3 = almost every day). The total score of the scale is 27 points, with 0 to 4 points indicating the absence of depression, 5 to 9 points for mild depression, 10 to 14 points for moderate depression, and 15 to 27 points for severe depression.

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4 A 17-item version of HAMD was used in this study, with a total score of 0 to 7 points
5 indicative of no depression, 8 to 17 points of mild depression, 18 to 24 points of
6 moderate depression, and >24 points of severe depression.
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10 As noted above, DSM-V was used as the gold standard for the diagnosis of
11 depression. The above questionnaires were collected by the same trained physician to
12 avoid selection bias.
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15 16 **Statistical analysis**

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19 In this cross-sectional study, data were processed and analyzed using SPSS version
20 20.0 (IBM, Armonk, NY). Listwise deletions were carried out to manage missing
21 values. Subgroup analysis was used to control confounding factors. Quantitative data
22 are presented as mean±standard deviation, and count data are expressed with
23 percentages. To calculate the internal consistency of HAMD and C-PHQ-9, we used
24 Cronbach's α . To derive the optimal cutoff points for HAMD and C-PHQ-9, we
25 performed receiver operating characteristic (ROC) analysis. We compared the areas
26 under the ROC curves (AUCs) to determine the respective abilities of HAMD and
27 C-PHQ-9 to diagnose depression. In all tests, statistical significance was defined as a
28 *P*-value of <0.05.
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39 **Patient and Public Involvement**

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42 Patients with psoriasis were included from the outpatient and inpatient departments of
43 the Affiliated Hospital of Southwest Medical University from January to February
44 2018. Patients with psoriasis were evaluated by professional dermatologists and met
45 the clinical diagnostic criteria for psoriasis. The survey was approved by the Ethics
46 Committee of the Affiliated Hospital of Southwest Medical University, and all
47 subjects signed the informed consent form. The sample size was determined by
48 retrieving previous studies.
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RESULTS

Patient characteristics

A total of 150 questionnaires were distributed in this survey, and 148 valid questionnaires were collected (response rate 98.67%). Each patient met the diagnostic criteria for psoriasis, and there were no other confounding factors such as systemic diseases and mental illness with a clear diagnosis. The study sample comprised 90 male (60.81%) and 58 female (31.19%) patients, with a mean age of 43.37 ± 17.46 (range 18 to 85) years. The mean disease course was 9.63 ± 7.85 (range 0.5 to 43) years. Table 1 outlines the sociodemographic variables considered in the study and the rate of depression with respect to each of these variables.

Table 1. Patient characteristics

Variables	Psoriasis patients n	C-PHQ-9(+) n	Positive rate/%	χ^2 value	P-value
Gender				0.009	0.926
Male	90	35	38.89		
Female	58	23	39.66		
Age/years				0.032	0.858
≤60	126	49	33.56		
>60	22	9	40.91		
Disease duration /years				8.984	0.003
≤10	91	27	29.67		

>10	57	31	54.39		
Marital status				0.814	0.666
Unmarried	44	15	34.09		
Married	100	41	41.00		
Divorced or widowed	4	2	50.00		
Cultural level				1.334	0.248
Junior high school and below	91	39	42.86		
High school and above	57	19	33.33		
Place of residence				0.613	0.434
City	58	25	43.10		
Rural	90	33	36.67		

Sub-analyses with men and women

To help identify particular populations in which the C-PHQ-9 is particularly useful by sub-analyses with men and women and based on disease duration. The results in table 2 and table 3 showed no statistically significant difference in the incidence of depression between men and women with the same disease duration ($P > 0.05$).

Table 2. Depression rate between men and women when the disease duration ≤ 10 years

Disease duration ≤ 10 years				
	Psoriasis patients	C-PHQ-9(+) n	χ^2 value	P-value
Male	57	17	0.002	0.967
Female	34	10		

Table 3. Depression rate between men and women when the disease duration > 10 years

Disease duration > 10 years				
	Psoriasis patients	C-PHQ-9(+) n	χ^2 value	P-value
Male	33	18	0.001	0.977
Female	24	13		

Incidence of depression in patients with psoriasis

This study identified 30 patients (20.27%) who met the DSM-V criteria for the diagnosis of depression, and 118 patients (79.73%) without depression. There was no

significant difference between the C-PHQ-9 (39.19%) and HAMD (31.09%) detection rates for depression ($\chi^2=2.14$, $P=0.15$) (Table 4).

Table 4. C-PHQ-9 and HAMD scale depression findings (n, %)

Scale	Non-depressed patients	Mild depression	Moderate depression	Severe depression
C-PHQ-9	90 (60.81)	37 (25.00)	15 (10.14)	6 (4.05)
HAMD	102 (68.91)	29 (19.59)	10 (6.76)	7 (4.73)

Trust level analysis

Homogeneity reliability

The internal consistency coefficient (Cronbach's α coefficient) of the C-PHQ-9 scale was 0.938. The correlation coefficient between each item and the total score of the scale ranged from 0.540 to 0.854, and the correlation coefficient between each item ranged from 0.376 to 0.933, all of which demonstrated a significant correlation ($P<0.01$) (Table 5).

Table 5. Correlation between items in C-PHQ-9 and each item and total score (r)

Items	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9
Q1	1.000								
Q2	0.608*	1.000							
Q3	0.749*	0.650*	1.000						
Q4	0.661*	0.788*	0.561*	1.000					
Q5	0.702*	0.606*	0.589*	0.634*	1.000				

Q6	0.625*	0.508*	0.591*	0.567*	0.680*	1.000			
Q7	0.490*	0.390*	0.431*	0.509*	0.589*	0.803*	1.000		
Q8	0.501*	0.376*	0.438*	0.527*	0.573*	0.804*	0.858*	1.000	
Q9	0.499*	0.376*	0.436*	0.543*	0.589*	0.804*	0.868*	0.933*	1.000
Total score	0.840*	0.839*	0.839*	0.854*	0.761*	0.683*	0.573*	0.575*	0.540*

Note: Q1 refers to the first score, Q2 refers to the second score, etc.; *P <0.01 (two-sided test).

Test reliability

The initial score and the retested C-PHQ-9 total score after 1 week were analyzed, and the correlation coefficient was 0.955 ($P < 0.01$).

Validity analysis

Validity

The consistency analysis between C-PHQ-9 and HAMD showed a kappa coefficient of 0.779. The two were divided into positive correlations, and the correlation coefficient was 0.504 ($P < 0.01$).

Structural validity

Principal component analysis showed that the KMO value was 0.877, and the Bartley spherical test statistic was 31130.97 ($P < 0.05$), indicating that there are common factors among the items, which is suitable for factor analysis. The principal component factor analysis was a one-factor structure, the extracted eigenvalue was 6.20, the variance of the factor was 68.88% of the total, and the factor load matrix coefficients of all the entries was greater than 0.572 (0.572 to 0.950).

ROC curve

A total of 148 subjects were evaluated using the DSM-V, including 30 patients with depression and 118 patients without depression, and DSM-V was used this as the standard for the ROC curve, with the maximum Youden index (sensitivity + specificity = 1). The best cutoff point for C-PHQ-9 was 9 points, with a sensitivity of 98.00% and a specificity of 90.80%. The AUC of C-PHQ-9 was 0.979 (95% confidence interval: 0.968 to 0.991) (Figure 1).

Comparison of the completion time of the two scales

In this study, the mean completion time for each C-PHQ-9 evaluation (2.02 ± 0.84 minutes) was significantly less than that for each HAMD (23.37 ± 3.21 minutes), and the difference was statistically significant ($t = -78.37$, $P < 0.001$).

DISCUSSION

About 300 million people worldwide are affected by depression,[10] with different prevalence rates in different countries, including about 8.1% in the US,[11] 8.7% in Argentina,[12] 14% in Brazil,[10] 5.9% to 9.8% in Germany,[13] 5.5% in Singapore,[14] and 5.9% to 13.2% in China.[15-16] Psoriasis is a common chronic inflammatory skin disease that has a notable impact on the lives of patients. A study that employed different survey populations and screening tools found that 9% to 55% of patients with psoriasis have depression.[8] However, currently, dermatologists are not very aware of depression, which results in undiagnosed depression in some psoriasis patients; thus, affecting the impact of psoriasis. Depression testing in patients with psoriasis is currently limited by three factors: (1) the high variability of currently available questionnaires, (2) the absence/lack of questionnaires designed and validated for patients with psoriasis disorders, and (3) the dermatologist's limited use and non-familiarity with questionnaires.[17] Therefore, it is necessary to find an evaluation scale for patients with psoriasis and depression, which is both specific and sensitive, and economical and time-saving.

Screening for depression refers to the use of a depression screening questionnaire to identify patients who may have depression but have not been diagnosed with the condition. PHQ-9 has been recommended by DSM-V for investigating depression and has been shown to have good reliability and validity in different populations,[18-20] but there are no reports on its use in patients with psoriasis disorders. In this study, 148 patients with psoriasis were investigated using the C-PHQ-9 scale. The rate of depression in patients with psoriasis using C-PHQ-9 scale was 39.19%. It is consistent with previous research results.[8] But after controlling the disease duration, there is no difference in the prevalence of depression between men and women. In future work, we will focus on whether C-PHQ-9 has a specific population that is particularly useful. The rate of depression was significantly higher in patients with a disease duration >10 years. This finding is consistent with other research results and seems reasonable because of the longstanding adverse effects of psoriasis in these patients.

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4 Specificity in this study was similar to that in previous studies and across reference
5 standards. Based on semi-structured interviews, the standard cutoff score of 9
6 maximized combined sensitivity and specificity, which yielded values of 98.00% and
7 90.80%, respectively. In this study, we hoped to find a simpler, more convenient and
8 efficient scale for dermatologists to evaluate the psychological state of patients with
9 psoriasis in clinical work, and to timely identify patients with depression, and the
10 results show the best truncation. The cutoff point is 9, the sensitivity and specificity
11 can reach 98% and 90.8%, which is slightly different from previous studies.
12 [21]Martin et al. found the best cutoff score is 10 , and this part of patients is the part
13 of patients who need psychological intervention by psychologists. Our results can
14 screen out some patients with early depression, and can take early psychological
15 intervention to avoid serious consequences. The Kappa coefficient between the
16 C-PHQ-9 and HAMD scales was 0.779. The two scales were divided into positive
17 correlations, and the correlation coefficient was 0.504, which indicates good
18 consistency. The detection of depression was higher with C-PHQ-9 and HAMD than
19 with DSM-V, which is consistent with previous studies, indicating that both have
20 good false-positive rates. The time to complete C-PHQ-9 was less than that taken to
21 complete HAMD.
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39 The main strength of this study is that all psoriasis patients were assessed using the
40 gold standard for evaluating depression. DSM-V and the C-PHQ-9 scale were
41 innovatively applied to patients with psoriasis. Moreover, the time to complete
42 C-PHQ-9 and HAMD was also assessed. However, the study was limited by its small
43 sample size and its cross-sectional and single-center design. In the future, randomized
44 controlled trials are needed to analyze factors related to psoriasis and assess the effect
45 of C-PHQ-9 in patients with psoriasis and depression.
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CONCLUSIONS

C-PHQ-9 has the advantages of fewer items, easier administration, better clarity, high screening efficiency, and having 9 diagnostic criteria for depression in DSM-V. PHQ-9 not only provides value for screening but can also assess the severity of depression, and the scale has obvious time and labor advantages over HAMD. Because of its simplicity, high sensitivity, and high specificity, we believe C-PHQ-9 should be strongly considered for use in the clinical setting for screening psoriasis patients with depression, with a recommended cutoff score of ≥ 9 .

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Competing interests: None.

Author contributions: Xin Ye and Hui-ling Shu were involved in the study design, study coordination, data analysis, and manuscript writing. Xia Feng, Xue-li Zhang and Deng-mei Xia contributed to the data analysis and manuscript writing. Bei Yu, Wen-yao Mi, and Zheng-qun Wang were involved in patient recruitment coordination and Chang-qiang Li was involved in the study design and critical revision of the manuscript.

Data sharing statement: No additional data are available.

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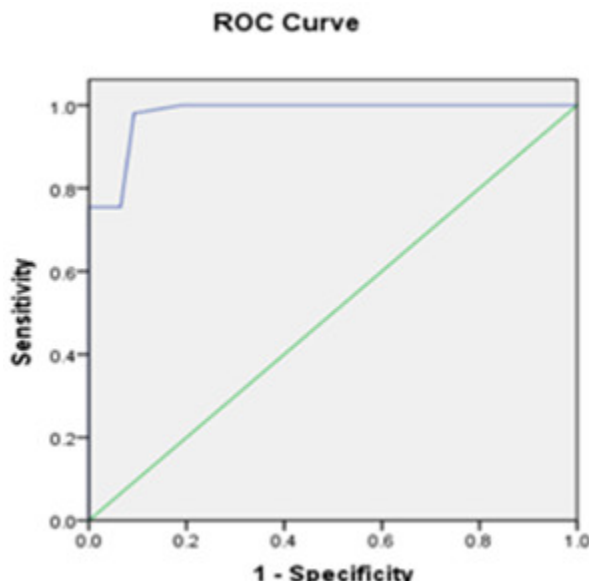
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13 **FIGURE LEGEND**

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16 Figure 1. ROC curve of C-PHQ-9

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18 Note: The blue line represents the ROC curve of C-PHQ-9, and the green line
19 represents the diagnostic reference line.
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ROC curve of C-PHQ-9
105x105mm (72 x 72 DPI)

STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation
Title and abstract	1-3	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	5-6	Explain the scientific background and rationale for the investigation being reported
Objectives	Page6,line20	State specific objectives, including any prespecified hypotheses
Methods		
Study design	Page7,line1	Present key elements of study design early in the paper
Setting	Page7,line4	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	Page8,line19	(a) Give the eligibility criteria, and the sources and methods of selection of participants
Variables	7-8	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	Page7*,line23	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	Page8,line4	Describe any efforts to address potential sources of bias
Study size	Page8,line24	Explain how the study size was arrived at
Quantitative variables	Page8,line8	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	Page8,line8	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses
Results		
Participants	Page9*,line2	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	Page9*,line11	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest
Outcome data	9*	Report numbers of outcome events or summary measures
Main results	Page12,line8	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included

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(b) Report category boundaries when continuous variables were categorized

(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period

Other analyses	Page10,line12	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
Discussion		
Key results	Page15,line21	Summarise key results with reference to study objectives
Limitations	Page16, line 22	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
Interpretation	Page16,line4	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
Generalisability	Page16, line 19	Discuss the generalisability (external validity) of the study results

*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

BMJ Open

Reliability and validity of the Chinese version of the Patient Health Questionnaire 9 (C-PHQ-9) in patients with psoriasis : a cross-sectional study

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Secondary Subject Heading:	Addiction, Anaesthesia, Cardiovascular medicine, Communication, Complementary medicine
Keywords:	C-PHQ-9, Reliability, Validity, Psoriasis < DERMATOLOGY, Depression

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4 **Reliability and validity of the Chinese version of the Patient Health**
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6 **Questionnaire 9 (C-PHQ-9) in patients with psoriasis: a**
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12 Xin Ye^{1#}, Hui-ling Shu^{1#}, Xia Feng¹, Deng-mei Xia¹, Zheng-qun Wang¹,
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ABSTRACT

Objective: To evaluate the clinical reliability and validity of the Chinese version of the Patient Health Questionnaire 9 (C-PHQ-9) in psoriasis patients.

Design: Cross-sectional study

Setting: Tertiary care center

Participants: Patients with psoriasis who has not a diagnosis of depression before. (n=148; mean age 43.37±17.46 years; female 31.19%).

Primary and secondary outcome measures: The primary outcome measures considered in this study were C-PHQ-9 and Hamilton Depression scale (HAMD). The American Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM-V) was used as the gold standard for the diagnosis of depression. Cronbach's α and test-retest reliability after 1 week were evaluated using reliability analysis and criterion validity and structural validity were assessed using validity analysis. Receiver operating characteristic (ROC) analysis was performed to detect the best demarcation score and diagnostic accuracy.

Results: Compared with DSM-V(27.27%),both C-PHQ-9 (39.19%) and HAMD (31.01%) had higher rates of detecting depression . The mean completion time for C-PHQ-9 evaluation (2.02±0.84 minutes) was significantly less than that for HAMD (23.37±3.21 minutes, $P<0.001$). Cronbach's α coefficient for the C-PHQ-9 was 0.938. The correlation coefficients of the nine items with the total scale ranged from 0.540 to 0.854, and the mean inter-item correlation coefficients ranged from 0.376 to 0.933. After a week, the retest coefficient was 0.955 ($P<0.01$). Principal component factor analysis showed that C-PHQ-9 identified a unifactorial structure. The best cutoff point was 9 points, sensitivity was 98.00%, and specificity was 90.80%. The area under the ROC curve was 0.979 (95% confidence interval: 0.968 to 0.991).

Conclusion: C-PHQ-9 has good reliability and validity for patients with psoriasis. And can be used for the primary screening of patients with psoriasis and

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3 depression. This scale has obvious time and labor advantages over the HAMD and
4 should be considered for use in clinical practice.
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8 *Key words:* C-PHQ-9; Reliability; Validity; Psoriasis; Depression
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STRENGTHS AND LIMITATIONS OF THIS STUDY

- The main strength of this study is that all psoriasis patients were assessed using the gold standard (DSM-V) tool for evaluating depression.
- The C-PHQ-9 scale was also innovatively applied to patients with psoriasis.
- Furthermore, the time to complete C-PHQ-9 and HAMD was also assessed.
- However, the study was limited by its small sample size.
- The study was also limited by its cross-sectional and single-center design.

For peer review only

INTRODUCTION

Psoriasis is a chronic inflammatory systemic disease with a strong genetic predisposition and autoimmune pathogenic traits that affects about 2% of the population.[1] Psoriasis is characterized by hyperproliferation of the epidermis resulting in thick, red, scaly lesions.[2] Itchiness, skin flaking, swelling, redness, pain and other manifestations frequently accompany the lesions, and the arthritic complications of the disease can cause pain and lead to loss of mobility and even disability.[3] Although the pathogenesis of psoriasis is not clear, it is currently believed to be mainly related to genetics, immunity, oxidative stress (OS), inflammatory response, and environment[4]. Psoriasis typically affects the skin, but may also affect the joints, and has been associated with a number of diseases. A study revealed that depression is a common complication of psoriasis, with an incidence of about 22.1%.[1] The impact of psoriasis on psychological and mental health is currently an important consideration due to the implications of the disease on social well-being and treatment. Patients with psoriasis have an increased prevalence of depression and anxiety and suicidal ideation. Interestingly, psoriasis treatment leads to improvement in anxiety symptoms.[5,6] Dantzer et al. Proposed a hypothesis of inflammatory cytokines for depression through a large number of animal experiments and clinical observations. Activated immune inflammatory pathways are now thought to participate in the development of depression. Some proinflammatory factors such as IL-1, TNF- α , and interferon- γ can cause psoriasis and also play an important role as neurotransmitters in depression.[7] The inflammatory response may be a common pathway for depression in patients with psoriasis.

Currently, there are more than 10 kinds of assessment scales for clinical depression. Different studies have shown that different assessment scales have different detection rates for depression.[8] The most widely used is the Hamilton Depression Scale (HAMD); However, owing to its complexity and need for professional input, it requires more labor and time. The Chinese version of the Patient Health Questionnaire 9 (C-PHQ-9) is a self-evaluation tool for the diagnosis and assessment of depression

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3 based on the major disorder of the Diagnostic and Statistical Manual of Mental
4 Disorders (4th Edition) (DSM-IV).[9]
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8 Despite the emergence of novel biological agents, most psoriasis can be effectively
9 controlled. However, due to the high price of biological agents, most psoriasis
10 patients fail to use biologics. So the symptoms of most psoriasis patients are not
11 effectively controlled. The symptoms of psoriasis has a profound impact on the
12 quality of life of patients, and patients often experience depression, anxiety, and even
13 suicidal behavior. These adverse emotions can further aggravate the condition of
14 patients with psoriasis through the nervous-endocrine system and the
15 nervous-immune system, forming a vicious circle. The "neurotransmitter hypothesis"
16 suggests that neurotransmitters such as norepinephrine (NE) and dopamine (DA) are
17 abnormally expressed in patients with depression. These neurotransmitters are
18 important components of the neuro-endocrine-immunomodulato
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30 -ry system, which can regulate the phagocytosis and proliferation activity of
31 lymphocytes and macrophages, and may promote the occurrence and development of
32 psoriasis. Therefore, clinicians should screen and detect patients with psoriasis early
33 and develop individualized psychosomatic treatment programs for patients with
34 psoriasis to adapt to the medical model under the new situation. However, the
35 diagnosis of depression in the dermatology clinic is difficult for health care
36 practitioners who are not qualified psychiatrists. In particular, professional, complex,
37 and time-consuming survey scales makes such diagnoses more difficult to achieve.
38 Therefore, it is necessary to identify an accurate and simple depression screening tool.
39 Considering the above, this study aimed to evaluate the clinical reliability and validity
40 of the Chinese version of the Patient Health Questionnaire 9 (C-PHQ-9) in screening
41 patients with psoriasis for depression.
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METHODS

Study Design

This study is a cross-sectional study. The study was conducted in accordance with the tenets of the Declaration of Helsinki. Written consent for the use of clinical data in aggregated form was obtained from all patients after they were informed about the study procedures. In this observational study, 148 patients with psoriasis were included from the outpatient and inpatient departments of The Affiliated Hospital of Southwest Medical University from January to February 2018. The diagnosis of depression was made by a psychiatrist using the American Diagnostic and Statistical Manual of Mental Disorders 5th edition (DSM-V), which is considered the gold standard for assessing depression. The psychiatrist determined each patient's HAMD score. The PHQ-9 is a self-evaluation tool for the major disorder based on the criteria of the Diagnostic and Statistical Manual of Mental Disorders (4th Edition). Every patient from the sample group who had an additional previous diagnosis of depression completed a questionnaire we created, which aimed to evaluate the C-PHQ-9 score, sociological data, and treatment satisfaction. The designated personnel received standardized training to follow specific instructions to guide the patients to complete the questionnaire and assessment. The C-PHQ-9 was carefully and completely filled out by each patient after reading the questionnaire. HAMD and DSM-V were assessed by two attending physicians. The psychiatrist completed the assessment and recorded the time it took to complete each questionnaire.

Measurements

The assessment range for C-PHQ-9 considers only the time period within the previous 2 weeks, with each symptom having a possible score of 0 to 3 points (0 = no, 1 = a few days, 2 = more than half of the days, 3 = almost every day). The total score of the scale is 27 points, with 0 to 4 points indicating the absence of depression, 5 to 9 points for mild depression, 10 to 14 points for moderate depression, and 15 to 27 points for severe depression.

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4 A 17-item version of HAMD was used in this study, with a total score of 0 to 7 points
5 indicative of no depression, 8 to 17 points of mild depression, 18 to 24 points of
6 moderate depression, and >24 points of severe depression.
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10 As noted above, DSM-V was used as the gold standard for the diagnosis of
11 depression. The above questionnaires were collected by the same trained physician to
12 avoid selection bias.
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15 16 **Statistical analysis**

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19 In this cross-sectional study, data were processed and analyzed using SPSS version
20 20.0 (IBM, Armonk, NY). Listwise deletions were carried out to manage missing
21 values. Subgroup analysis was used to control confounding factors. Quantitative data
22 are presented as mean±standard deviation, and count data are expressed with
23 percentages. To calculate the internal consistency of HAMD and C-PHQ-9, we used
24 Cronbach's α . To derive the optimal cutoff points for HAMD and C-PHQ-9, we
25 performed receiver operating characteristic (ROC) analysis. We compared the areas
26 under the ROC curves (AUCs) to determine the respective abilities of HAMD and
27 C-PHQ-9 to diagnose depression. In all tests, statistical significance was defined as a
28 *P*-value of <0.05.
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39 **Patient and Public Involvement**

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42 Patients with psoriasis were included from the outpatient and inpatient departments of
43 the Affiliated Hospital of Southwest Medical University from January to February
44 2018. Patients with psoriasis were evaluated by professional dermatologists and met
45 the clinical diagnostic criteria for psoriasis. The survey was approved by the Ethics
46 Committee of the Affiliated Hospital of Southwest Medical University, and all
47 subjects signed the informed consent form. The sample size was determined by
48 retrieving previous studies.
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RESULTS

Patient characteristics

A total of 150 questionnaires were distributed in this survey, and 148 valid questionnaires were collected (response rate 98.67%). Each patient met the diagnostic criteria for psoriasis, and there were no other confounding factors such as systemic diseases and mental illness with a clear diagnosis. The study sample comprised 90 male (60.81%) and 58 female (31.19%) patients, with a mean age of 43.37 ± 17.46 (range 18 to 85) years. The mean disease course was 9.63 ± 7.85 (range 0.5 to 43) years. Table 1 outlines the sociodemographic variables considered in the study and the rate of depression with respect to each of these variables.

Table 1. Patient characteristics

Variables	Psoriasis patients n	C-PHQ-9(+) n	Positive rate/%	χ^2 value	P-value
Gender				0.009	0.926
Male	90	35	38.89		
Female	58	23	39.66		
Age/years				0.032	0.858
≤60	126	49	33.56		
>60	22	9	40.91		
Disease duration /years				8.984	0.003
≤10	91	27	29.67		

>10	57	31	54.39		
Marital status				0.814	0.666
Unmarried	44	15	34.09		
Married	100	41	41.00		
Divorced or widowed	4	2	50.00		
Cultural level				1.334	0.248
Junior high school and below	91	39	42.86		
High school and above	57	19	33.33		
Place of residence				0.613	0.434
City	58	25	43.10		
Rural	90	33	36.67		

Sub-analyses with men and women

To help identify particular populations in which the C-PHQ-9 is particularly useful by sub-analyses with men and women and based on disease duration. The results in table 2 and table 3 showed no statistically significant difference in the incidence of depression between men and women with the same disease duration ($P > 0.05$).

Table 2. Depression rate between men and women when the disease duration ≤ 10 years

Disease duration ≤10 years				
	Psoriasis patients	C-PHQ-9(+) n	χ^2 value	P-value
Male	57	17	0.002	0.967
Female	34	10		

Table 3. Depression rate between men and women when the disease duration >10 years

Disease duration >10 years				
	Psoriasis patients	C-PHQ-9(+) n	χ^2 value	P-value
Male	33	18	0.001	0.977
Female	24	13		

Incidence of depression in patients with psoriasis

This study identified 30 patients (20.27%) who met the DSM-V criteria for the diagnosis of depression, and 118 patients (79.73%) without depression. There was no

significant difference between the C-PHQ-9 (39.19%) and HAMD (31.09%) detection rates for depression ($\chi^2=2.14$, $P=0.15$) (Table 4).

Table 4. C-PHQ-9 and HAMD scale depression findings (n, %)

Scale	Non-depressed patients	Mild depression	Moderate depression	Severe depression
C-PHQ-9	90 (60.81)	37 (25.00)	15 (10.14)	6 (4.05)
HAMD	102 (68.91)	29 (19.59)	10 (6.76)	7 (4.73)

Trust level analysis

Homogeneity reliability

The internal consistency coefficient (Cronbach's α coefficient) of the C-PHQ-9 scale was 0.938. The correlation coefficient between each item and the total score of the scale ranged from 0.540 to 0.854, and the correlation coefficient between each item ranged from 0.376 to 0.933, all of which demonstrated a significant correlation ($P<0.01$) (Table 5).

Table 5. Correlation between items in C-PHQ-9 and each item and total score (r)

Items	Q1	Q2	Q3	Q4	Q5	Q6	Q7	Q8	Q9
Q1	1.000								
Q2	0.608*	1.000							
Q3	0.749*	0.650*	1.000						
Q4	0.661*	0.788*	0.561*	1.000					
Q5	0.702*	0.606*	0.589*	0.634*	1.000				

Q6	0.625*	0.508*	0.591*	0.567*	0.680*	1.000			
Q7	0.490*	0.390*	0.431*	0.509*	0.589*	0.803*	1.000		
Q8	0.501*	0.376*	0.438*	0.527*	0.573*	0.804*	0.858*	1.000	
Q9	0.499*	0.376*	0.436*	0.543*	0.589*	0.804*	0.868*	0.933*	1.000
Total score	0.840*	0.839*	0.839*	0.854*	0.761*	0.683*	0.573*	0.575*	0.540*

Note: Q1 refers to the first score, Q2 refers to the second score, etc.; *P <0.01 (two-sided test).

Test reliability

The initial score and the retested C-PHQ-9 total score after 1 week were analyzed, and the correlation coefficient was 0.955 ($P<0.01$).

Validity analysis

Validity

The consistency analysis between C-PHQ-9 and HAMD showed a kappa coefficient of 0.779. The two were divided into positive correlations, and the correlation coefficient was 0.504 ($P<0.01$).

Structural validity

Principal component analysis showed that the KMO value was 0.877, and the Bartley spherical test statistic was 31130.97 ($P<0.05$), indicating that there are common factors among the items, which is suitable for factor analysis. The principal component factor analysis was a one-factor structure, the extracted eigenvalue was 6.20, the variance of the factor was 68.88% of the total, and the factor load matrix coefficients of all the entries was greater than 0.572 (0.572 to 0.950).

ROC curve

A total of 148 subjects were evaluated using the DSM-V, including 30 patients with depression and 118 patients without depression, and DSM-V was used this as the standard for the ROC curve, with the maximum Youden index (sensitivity + specificity = 1). The best cutoff point for C-PHQ-9 was 9 points, with a sensitivity of 98.00% and a specificity of 90.80%. The AUC of C-PHQ-9 was 0.979 (95% confidence interval: 0.968 to 0.991) (Figure 1).

Comparison of the completion time of the two scales

In this study, the mean completion time for each C-PHQ-9 evaluation (2.02 ± 0.84 minutes) was significantly less than that for each HAMD (23.37 ± 3.21 minutes), and the difference was statistically significant ($t = -78.37$, $P < 0.001$).

DISCUSSION

About 300 million people worldwide are affected by depression,[10] with different prevalence rates in different countries, including about 8.1% in the US,[11] 8.7% in Argentina,[12] 14% in Brazil,[10] 5.9% to 9.8% in Germany,[13] 5.5% in Singapore,[14] and 5.9% to 13.2% in China.[15-16] Psoriasis is a common chronic inflammatory skin disease that has a notable impact on the lives of patients. A study that employed different survey populations and screening tools found that 9% to 55% of patients with psoriasis have depression.[8] However, currently, dermatologists are not very aware of depression, which results in undiagnosed depression in some psoriasis patients; thus, affecting the treatment of psoriasis. Depression testing in patients with psoriasis is currently limited by three factors: (1) the high variability of currently available questionnaires, (2) the absence/lack of questionnaires designed and validated for patients with psoriasis disorders, and (3) the dermatologist's limited use and non-familiarity with questionnaires.[17] Therefore, it is necessary to find an evaluation scale for patients with psoriasis and depression, which is both specific and sensitive, and economical and time-saving.

Screening for depression refers to the use of a depression screening questionnaire to identify patients who may have depression but have not been diagnosed with the condition. PHQ-9 has been recommended by DSM-V for investigating depression and has been shown to have good reliability and validity in different populations,[18-20] but there are no reports on its use in patients with psoriasis disorders. In this study, 148 patients with psoriasis were investigated using the C-PHQ-9 scale. The rate of depression in patients with psoriasis using C-PHQ-9 scale was 39.19%. It is consistent with previous research results.[8] But after controlling the disease duration, there is no difference in the prevalence of depression between men and women. In future work, we will focus on whether C-PHQ-9 has a specific population that is particularly useful. The rate of depression was significantly higher in patients with a disease duration >10 years. This finding is consistent with other research results and seems reasonable because of the longstanding adverse effects of psoriasis in these patients.

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4 Specificity in this study was similar to that in previous studies and across reference
5 standards. Based on semi-structured interviews, the standard cutoff score of 9
6 maximized combined sensitivity and specificity, which yielded values of 98.00% and
7 90.80%, respectively. In this study, we hoped to find a simpler, more convenient and
8 efficient scale for dermatologists to evaluate the psychological state of patients with
9 psoriasis in clinical work, and to timely identify patients with depression, and the
10 results show the best truncation. The cutoff point is 9, the sensitivity and specificity
11 can reach 98% and 90.8%, which is slightly different from previous studies.
12 [21]Martin et al. found the best cutoff score is 10 , and this part of patients is the part
13 of patients who need psychological intervention by psychologists. Our results can
14 screen out some patients with early depression, and can take early psychological
15 intervention to avoid serious consequences. The Kappa coefficient between the
16 C-PHQ-9 and HAMD scales was 0.779. The two scales were divided into positive
17 correlations, and the correlation coefficient was 0.504, which indicates good
18 consistency. The detection of depression was higher with C-PHQ-9 and HAMD than
19 with DSM-V, which is consistent with previous studies, indicating that both have
20 good false-positive rates. The time to complete C-PHQ-9 was less than that taken to
21 complete HAMD.
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39 The main strength of this study is that all psoriasis patients were assessed using the
40 gold standard for evaluating depression. DSM-V and the C-PHQ-9 scale were
41 innovatively applied to patients with psoriasis. Moreover, the time to complete
42 C-PHQ-9 and HAMD was also assessed. However, the study was limited by its small
43 sample size and its cross-sectional and single-center design. In the future, randomized
44 controlled trials are needed to analyze factors related to psoriasis and assess the effect
45 of C-PHQ-9 in patients with psoriasis and depression.
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CONCLUSIONS

C-PHQ-9 has the advantages of fewer items, easier administration, better clarity, high screening efficiency, and having 9 diagnostic criteria for depression in DSM-V. PHQ-9 not only provides value for screening but can also assess the severity of depression, and the scale has obvious time and labor advantages over HAMD. Because of its simplicity, high sensitivity, and high specificity, we believe C-PHQ-9 should be strongly considered for use in the clinical setting for screening psoriasis patients with depression, with a recommended cutoff score of ≥ 9 .

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Competing interests: None.

Author contributions: Xin Ye and Hui-ling Shu were involved in the study design, study coordination, data analysis, and manuscript writing. Xia Feng, Xue-li Zhang and Deng-mei Xia contributed to the data analysis and manuscript writing. Bei Yu, Wen-yao Mi, and Zheng-qun Wang were involved in patient recruitment coordination and Chang-qiang Li was involved in the study design and critical revision of the manuscript.

Data sharing statement: No additional data are available.

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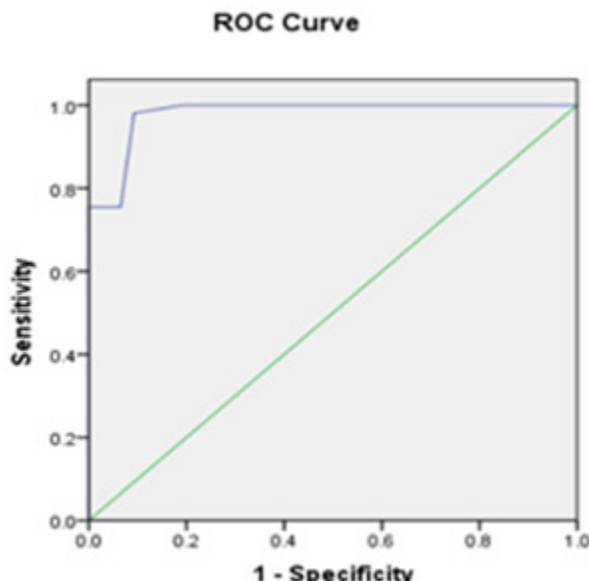
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13 **FIGURE LEGEND**

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16 Figure 1. ROC curve of C-PHQ-9

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18 Note: The blue line represents the ROC curve of C-PHQ-9, and the green line
19 represents the diagnostic reference line.
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ROC curve of C-PHQ-9
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STROBE Statement—Checklist of items that should be included in reports of *cross-sectional studies*

	Item No	Recommendation
Title and abstract	1-3	(a) Indicate the study's design with a commonly used term in the title or the abstract (b) Provide in the abstract an informative and balanced summary of what was done and what was found
Introduction		
Background/rationale	5-6	Explain the scientific background and rationale for the investigation being reported
Objectives	Page6,line20	State specific objectives, including any prespecified hypotheses
Methods		
Study design	Page7,line1	Present key elements of study design early in the paper
Setting	Page7,line4	Describe the setting, locations, and relevant dates, including periods of recruitment, exposure, follow-up, and data collection
Participants	Page8,line19	(a) Give the eligibility criteria, and the sources and methods of selection of participants
Variables	7-8	Clearly define all outcomes, exposures, predictors, potential confounders, and effect modifiers. Give diagnostic criteria, if applicable
Data sources/ measurement	Page7*,line23	For each variable of interest, give sources of data and details of methods of assessment (measurement). Describe comparability of assessment methods if there is more than one group
Bias	Page8,line4	Describe any efforts to address potential sources of bias
Study size	Page8,line24	Explain how the study size was arrived at
Quantitative variables	Page8,line8	Explain how quantitative variables were handled in the analyses. If applicable, describe which groupings were chosen and why
Statistical methods	Page8,line8	(a) Describe all statistical methods, including those used to control for confounding (b) Describe any methods used to examine subgroups and interactions (c) Explain how missing data were addressed (d) If applicable, describe analytical methods taking account of sampling strategy (e) Describe any sensitivity analyses
Results		
Participants	Page9*,line2	(a) Report numbers of individuals at each stage of study—eg numbers potentially eligible, examined for eligibility, confirmed eligible, included in the study, completing follow-up, and analysed (b) Give reasons for non-participation at each stage (c) Consider use of a flow diagram
Descriptive data	Page9*,line11	(a) Give characteristics of study participants (eg demographic, clinical, social) and information on exposures and potential confounders (b) Indicate number of participants with missing data for each variable of interest
Outcome data	9*	Report numbers of outcome events or summary measures
Main results	Page12,line8	(a) Give unadjusted estimates and, if applicable, confounder-adjusted estimates and their precision (eg, 95% confidence interval). Make clear which confounders were adjusted for and why they were included

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(b) Report category boundaries when continuous variables were categorized

(c) If relevant, consider translating estimates of relative risk into absolute risk for a meaningful time period

Other analyses	Page10,line12	Report other analyses done—eg analyses of subgroups and interactions, and sensitivity analyses
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Discussion

Key results	Page15,line21	Summarise key results with reference to study objectives
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Limitations	Page16, line 22	Discuss limitations of the study, taking into account sources of potential bias or imprecision. Discuss both direction and magnitude of any potential bias
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Interpretation	Page16,line4	Give a cautious overall interpretation of results considering objectives, limitations, multiplicity of analyses, results from similar studies, and other relevant evidence
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Generalisability	Page16, line 19	Discuss the generalisability (external validity) of the study results
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*Give information separately for exposed and unexposed groups.

Note: An Explanation and Elaboration article discusses each checklist item and gives methodological background and published examples of transparent reporting. The STROBE checklist is best used in conjunction with this article (freely available on the Web sites of PLoS Medicine at <http://www.plosmedicine.org/>, Annals of Internal Medicine at <http://www.annals.org/>, and Epidemiology at <http://www.epidem.com/>). Information on the STROBE Initiative is available at www.strobe-statement.org.

Correction: *Reliability and validity of the Chinese version of the Patient Health Questionnaire-9 (C-PHQ-9) in patients with psoriasis: a cross-sectional study*

Ye X, Shu H, Feng X, *et al.* Reliability and validity of the Chinese version of the Patient Health Questionnaire-9 (C-PHQ-9) in patients with psoriasis: a cross-sectional study. *BMJ Open* 2020;10:e033211. doi: 10.1136/bmjopen-2019-033211.

This article was previously published with an error. The funding information in the published article was incomplete. The updated funding information is stated below:

The study of Neuroendocrine basis and comorbidity mechanism in psoriasis patients with depression (LuZhou Science and Technology Department-Southwest Medical University joint Project (090300021424)).

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