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RESEARCH ARTICLE



## Short-term effectiveness and potential factors of ustekinumab based on real-world data in Chinese psoriasis patients

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### ABSTRACT

**Background:** As one of the most effective biologic treatments for psoriasis, the short-term effectiveness of ustekinumab has yet to be studied extensively.

**Objective:** The purpose of this study was to evaluate the short-term effectiveness and potential factors within four weeks after the first-dose ustekinumab treatment based on real-world data.

**Methods:** The study enrolled 98 patients with moderate-to-severe psoriasis, given ustekinumab 45 mg at week 0, week 4, and then every 12 weeks. Based on clinical data collected at baseline and week 4, we investigated the short-term effectiveness of ustekinumab after the first dose and potential factors associated with the treatment. For evaluation, we collected demographic information, body data, medical history, laboratory examination results, Psoriasis Area and Severity Index (PASI), body surface area (BSA), and dermatology life quality index (DLQI). Response rates were calculated based on the number of patients that achieved a 75/90/100% reduction in PASI (PASI 75/90/100), and the primary treatment goal was to achieve PASI 75.

**Results:** The response rates for PASI 75/90/100 at week 4 were 30.5%, 18.9%, and 16.8%, respectively. For PASI 75, the response rate was higher in patients without metabolic syndrome (MS) (without MS vs. with MS: 36.9% vs. 5.9%,  $p=0.013$ ); the serum triglyceride (TG) level was significantly lower in patients achieving PASI 75 (expressed as mean  $\pm$  standard deviation, achieved vs. unachieved:  $1.82 \pm 1.79$  vs.  $3.59 \pm 8.89$ ,  $p=0.010$ ). For PASI 100, the response rates were higher in female patients (female vs. male: 26.3% vs. 10.5%,  $p=0.044$ ) and patients with a family history of psoriasis (with family history vs. without family history: 44.4% vs. 13.9%,  $p=0.042$ ). In addition, the possibility of achieving PASI 75/90/100 went up along with the serum high-density lipoprotein cholesterol (HDL-C) level (expressed as adjusted odds ratio < 95% confidence interval>: PASI 75:  $28.484 < 2.035-248.419$ >,  $p=0.011$ ; PASI 90:  $28.226 < 2.828-281.729$ >,  $p=0.004$ ; PASI 100:  $12.175 < 1.876-79.028$ >,  $p=0.009$ ).

**Conclusion:** In this study, nearly one-third of patients achieved PASI 75 after only the first-dose ustekinumab treatment. Sex, family history of psoriasis, MS, serum TG level might affect the short-term effectiveness, and serum HDL-C level may be a potential factor. The possibility of achieving treatment goals (PASI 75/90/100) at week 4 increased along with serum HDL-C levels.

### ARTICLE HISTORY

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### KEYWORDS


Psoriasis; biologics; ustekinumab; short-term effectiveness; real-world data

### Introduction

Psoriasis is a chronic immune-mediated papulosquamous skin disease consisting of systemic manifestations (1), with a prevalence being 0.51%–11.43% of the worldwide population (2,3). Various comorbidities could be accompanied with psoriasis, including metabolic syndrome (MS), which includes central obesity, hyperglycemia or diabetes mellitus, dyslipidemia, and hypertension (4–6), and is associated with increased disease severity of psoriasis, impaired

biologic therapeutic response, and the decrease of effectiveness persistence (6–9).

Biologics that inhibit specific target cytokines, such as interleukin (IL)-12, IL-17, IL-23, and tumor necrosis factor- $\alpha$  (TNF- $\alpha$ ) (9), have become popular and effective treatment choices. Ustekinumab (Stelara, Janssen Biotech) is specifically blocking the p40 subunit in IL-23 (10, 11), inhibiting the inflammatory cascade amplification, diminishing primary signals to pathologically drive the development of psoriasis (12,13). Compared with other biologics approved

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in the medicine market, ustekinumab requires less frequency and dosage, with a relatively long interval between administrations (14). Thus, commonly it is the long-term rather than the short-term efficacy that has been focused more in randomized clinical trials (RCTs) and observational clinical trials (15–20). More rarely, so far, there has not been much research focusing on the effects that MS causes on short-term efficacy.

This study aims to collect real-world data after the first-dose treatment of ustekinumab among Chinese patients to analyze the short-term effectiveness. Also, we intend to investigate whether the factors related to MS or other clinical characteristics may affect short-term effectiveness.

## Methods

### Patients and materials

This study enrolled moderate-to-severe psoriasis patients consecutively at the Department of Dermatology in Xiangya Hospital of Central South University from January to October 2022. Patients were required to accept the first dose and follow-up treatments at our hospital except for special conditions. The washout period was not required between medication switches unless the reason was adverse events appearance (21,22), in which case the washout period for previously used systematic drugs ranged from 1 month to 3 months (3–4 half-life periods of the former drug). A series of premedical examinations were done for every patient to ensure no contraindication for ustekinumab. The routine treatment dosage of ustekinumab is 45 mg (patients with weight <100 kg) or 90 mg (patients with weight ≥100 kg) every time; the frequency of administration is week 0, week 4, and then every 12 weeks (Q12W) (17,18).

Ustekinumab is applicable to adult patients with moderate-to-severe plaque psoriasis, in the condition of having contraindications or intolerance to or failing to respond to cyclosporine, methotrexate (MTX) or psoralen and ultraviolet A (PUVA) and other systematic treatments (23). All patients were informed of the potential risks, theoretical benefits, and possibilities of ineffectiveness.

Patients were diagnosed by experienced dermatologists that were experts in psoriasis. Except for diagnosis, other clinical data collected consisted of demographic characteristics (age and sex) and clinical characteristics. The latter one consisted of body data (height, weight, waist circumference, and blood pressure), medical history, laboratory examination results, Psoriasis Area and Severity Index (PASI, scores range from 0 to 72 with higher scores indicating greater disease severity), body surface area (BSA), and dermatology life quality index (DLQI, scores range from 0 to 30 with higher scores indicating more significant effects on daily life). Besides, the family history of psoriasis was assessed among first-degree and second-degree relatives. The laboratory examination results included records of fasting serum lipids and fasting serum glucose. Metabolic syndrome was defined according to the Chinese guidelines, meeting at least three of the following criteria: (1) abdominal obesity (elevated waist circumference: ≥90 cm in males or ≥85 cm in females); (2) elevated fasting blood glucose (≥6.1 mmol/L) or medical treatment for hyperglycemia; (3) elevated blood pressure (systolic/diastolic blood pressure ≥130/85 mmHg) or medical treatment for a history of hypertension; (4) elevated fasting triglyceride (≥1.7 mmol/L); and (5) low fasting high-density lipoprotein cholesterol (HDL-C, <1.0 mmol/L) (24).

PASI, BSA, and DLQI were recorded to reflect disease severity. Follow-up visits were completed after the first-dose

treatment at week 4 before the second dose injected. Adverse events (AEs) and treatment discontinuation reasons were also recorded. Evaluations mentioned above were assessed blindly by experienced dermatologists to ensure reliability. The response rates were calculated based on the number of patients that achieved  $a \geq 75/90/100\%$  reduction in PASI (PASI 75/90/100), and the primary treatment goal was to achieve PASI 75. Effectiveness evaluations were only analyzed among data that could be observed, while patients not eligible were not included.

This study was conducted by the principles of the Declaration of Helsinki and approved by the Ethics Committee of Xiangya Hospital of Central South University (approval number: 2018121106). Before participation, all the adult patients have provided written informed consent confirmed by themselves; patients under 18 also have provided written informed consent approved by their parents or legal guardians.

### Statistical analyses

Descriptive statistics were calculated for continuous quantitative variables and expressed as mean  $\pm$  standard deviation (mean  $\pm$  SD). For categorical variables, frequencies were calculated and defined as frequency (percentages) ( $n(\%)$ ). Considering the relatively small data quantity, the Shapiro-Wilk test was used for the normality distribution test. T-test and Mann-Whitney U-test were conducted to analyze statistical differences for continuous variables meeting normal or non-normal distribution. The Chi-Square test was used for statistical difference and stratified analysis of response rates for categorical variables. The Fisher's precision probability test was used when the Chi-Square test was not applicable (the sample size  $n < 40$  or the expected frequency  $T < 5$ ). Bivariate logistic regression was conducted among factors significantly different between groups divided by the achievement of effectiveness indicators to reflect the association. All statistical analyses were accomplished in SPSS 26.0, and charts were drawn in GraphPad Prism 9.3.  $p < 0.05$  was considered statistically significant.

## Results

### Baseline characteristics

The demographic and clinical characteristics at baseline of all patients enrolled are summarized in Table 1. Our study recruited 98 patients receiving at least one ustekinumab treatment (Table 1).

The average age of all the patients included is 42 ( $42.0 \pm 14.0$ ) years old. The average onset age is 31 ( $30.8 \pm 14.8$ ) years old, with an average disease duration of 11 ( $11.2 \pm 9.5$ ) years. One-tenth of the patients (9/90) had a family history of psoriasis. As for the history of other medication administration, all of the patients had received topical drugs before, 7 patients had previously received other biologics (2 of adalimumab, 3 of secukinumab, and 2 of ixekizumab), which all aim at other target cytokines (TNF- $\alpha$  and IL-17). Reasons for changing to ustekinumab treatment included ineffectiveness ( $n=6$ ) and adverse events ( $n=1$ , eczema). Among 83 patients with laboratory examination results preserved in our medical record system, 17 (20.5%) patients were accompanied by MS at baseline. The average values (expressed as mean  $\pm$  SD) of PASI, BSA, and DLQI at baseline were  $9.4 \pm 4.8$ ,  $11.2 \pm 8.7$  and  $7.4 \pm 5.0$  respectively.

**Table 1.** Baseline characteristics of all the patients included.

Characteristics	Patients included (n=98)
Age (year), mean $\pm$ SD	42.0 $\pm$ 14.0
Age at onset (year), mean $\pm$ SD	30.8 $\pm$ 14.8
Disease duration (year), mean $\pm$ SD	11.2 $\pm$ 9.5
Sex (male), n (%)	58(59.8)
Family history of psoriasis, n (%)	9/90(10.0)
History of smoking, n (%)	35/90(35.9)
History of alcohol intake, n (%)	35/90(35.9)
History of other biologic administration, n (%)	7(6.4)
Adalimumab	2(1.8)
Ixekizumab	3(2.8)
Secukinumab	2(1.8)
Metabolic syndrome	17/83(20.5)
PASI at baseline, mean $\pm$ SD	9.4 $\pm$ 4.8
BSA at baseline, mean $\pm$ SD	11.2 $\pm$ 8.7
DLQI at baseline, mean $\pm$ SD	7.4 $\pm$ 5.0

SD: standard deviation; WHR: waist-to-hip ratio; BMI: body mass index; SBP: systolic blood pressure; DBP: diastolic blood pressure; PASI: Psoriasis Area and Severity Index; BSA: body surface area. DLQI: Dermatology Life Quality Index.

**Table 2.** Efficacy responses at week 4 after single-dose treatment.

Outcome measurements	Baseline (n=98)	At week 4 (n=95)
PASI, mean $\pm$ SD	9.4 $\pm$ 4.8	3.7 $\pm$ 3.1
PASI reduction, mean $\pm$ SD	N/A	5.9 $\pm$ 4.6
PASI 75, n (%)	N/A	29(30.5)
PASI 90, n (%)	N/A	18(18.9)
PASI 100, n (%)	N/A	16(16.8)
BSA, mean $\pm$ SD	11.2 $\pm$ 8.5	4.8 $\pm$ 5.5
BSA reduction, mean $\pm$ SD	N/A	4.6 $\pm$ 5.4
DLQI, mean $\pm$ SD	7.6 $\pm$ 4.8	2.7 $\pm$ 3.5
DLQI reduction, mean $\pm$ SD	N/A	4.9 $\pm$ 4.8
DLQI 0/1, n (%)	9(9.2)	44(46.3)

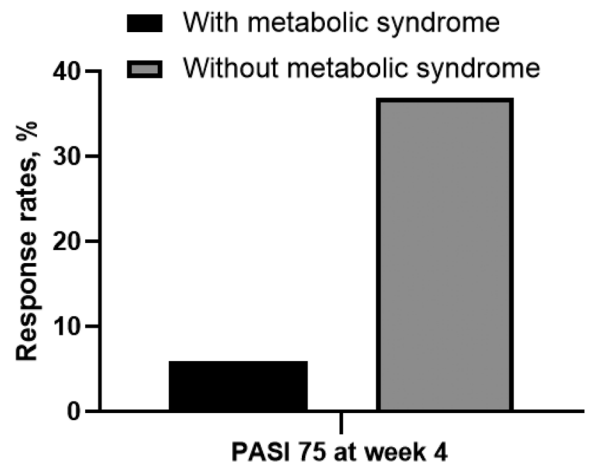
PASI: Psoriasis Area and Severity Index; SD: standard deviation; PASI 75/90/100:  $\geq$ 90/100% reduction in PASI; BSA: body surface area; DLQI: Dermatology Life Quality Index; N/A: not available.

### Effectiveness

To reveal the effectiveness both on the disease severity and the quality of life, we summarized the numerical variations in PASI, BSA, and DLQI. All patients enrolled were included in the effectiveness analyses. Notably, all 98 patients had completed the evaluation at baseline. In comparison, 3 patients failed to come to our hospital in person to meet the follow-up at week 4 (2 patients due to the local epidemic prevention and control policies, and 1 patient due to discontinuation caused by transaminase increasing).

The changes in PASI and BSA reflected the skin lesion severity. The mean value of PASI decreased from 9.4 at baseline to 3.7 at week 4, with the average PASI reduction of 5.9 after the first dose over 4 weeks, showing an apparent downward trend (Table 2). The percentages of average PASI reduction (compared to baseline) were 60.1%. The response rate of patients achieving the primary goal (PASI 75) after the first dose was 30.5%. The percentages of patients achieving PASI 90/100 at week 4 were 18.9% and 16.8%, respectively (Table 2). Meanwhile, the average value of BSA declined from 11.2 at baseline to 4.8 at week 4, with an average reduction of 4.6 (Table 2).

From the perspective of changes in quality of life, the mean value of DLQI at baseline and week 4 were 7.6 and 2.7, respectively (Table 1), with an average reduction of 4.9, also showing an apparent downward trend (Table 2). Besides, the percentages of patients achieving DLQI 0/1 were raised from 9.2% at baseline to 46.3% at week 4.



**Figure 1.** Proportion of patients achieving PASI 75 at week 4 in groups with or without metabolic syndrome. With metabolic syndrome vs. without metabolic syndrome: 5.9% vs. 36.9%,  $p=0.010$ . PASI 75:  $\geq$ 75% reduction in Psoriasis Area and Severity Index.

**Table 3.** Results of difference analysis between groups whether achieving PASI 75/90/100 at week 4.

Characteristic (n=98)	P value		
	PASI 75	PASI 90	PASI 100
Sex	0.524	0.135	0.044
Age	0.566	0.635	0.441
Age at onset	0.445	0.293	0.196
Disease duration	0.108	0.543	0.560
Early onset	0.309	0.378	0.542
Family history of psoriasis	0.117	0.066	0.042
Smoking	0.871	0.494	0.984
Alcohol intake	0.787	1.000	0.752
Metabolic syndrome complication	0.013	0.171	0.280
Central obesity	0.260	0.253	0.220
SBP	0.068	0.396	0.241
DBP	0.130	0.956	0.755
TG	0.010	0.196	0.234
HDL-C	<0.001	<0.001	0.002
Blood glucose	0.497	0.627	0.592
ESR	0.148	0.289	0.098
CRP	0.316	0.234	0.761
PASI at baseline	0.872	0.861	0.623
BSA at baseline	0.920	0.676	0.176
DLQI at baseline	0.248	0.178	0.065

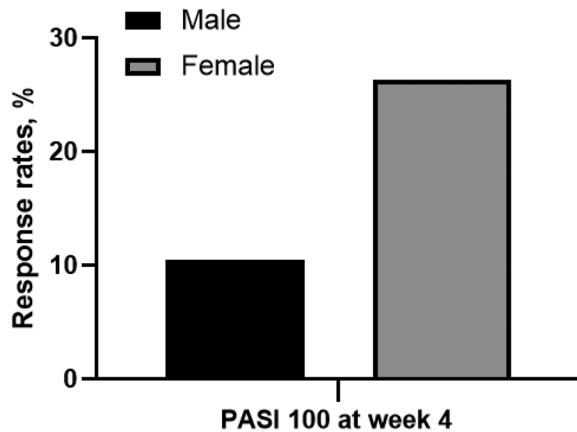
SBP: systolic blood pressure; DBP: diastolic blood pressure; TG: triglyceride; HDL-C: high density lipoprotein cholesterol; ESR: erythrocyte sedimentation rate; CRP: C-reactive protein; PASI: Psoriasis Area and Severity Index; BSA: body surface area; DLQI: Dermatology Life Quality Index; PASI 75/90/100:  $\geq$ 75/90/100% reduction in PASI. P value <0.05 was considered statistically significant.

### Factors associated with medication responses

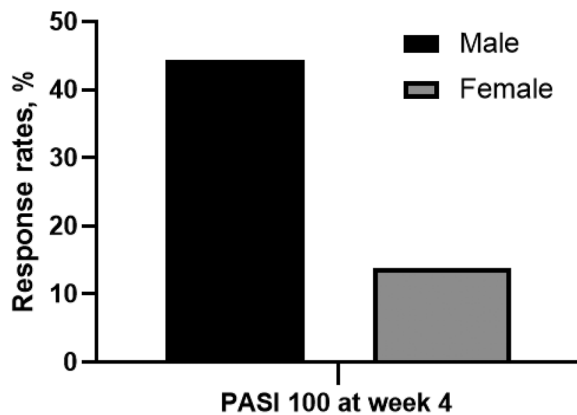
We conducted univariate analyses to screen potential factors that may be associated with short-term effectiveness. For the primary treatment goal (PASI 75), the results indicated that the response rate was higher in patients without MS (without MS vs. with MS: 36.9% vs. 5.9%,  $p=0.013$ ) (Figure 1). Also, the serum TG level was significantly lower in patients achieving the primary treatment goal (mean  $\pm$  SD, PASI 75 achieved vs. PASI 75 unachieved:  $1.82 \pm 1.79$  vs.  $3.59 \pm 8.89$ ,  $p=0.010$ ) (Table 3). For the skin lesion clearance (PASI 100), the response rates were higher in female patients (female vs. male: 26.3% vs. 10.5%,  $p=0.044$ ) (Figure 2) and patients with a family history of psoriasis (with family history vs. without family history: 44.4% vs. 13.9%,  $p=0.042$ ) (Figure 3).

Notably, the serum HDL-C levels were significantly higher in patients achieving PASI 75/90/100 respectively (mean $\pm$ SD, achieved vs. unachieved: PASI 75: 1.48 $\pm$ 0.47 vs. 1.17 $\pm$ 0.24,  $p<0.001$ ; PASI 90: 1.57 $\pm$ 0.55 vs. 1.09 $\pm$ 0.25,  $p<0.001$ ; PASI 100: 1.57 $\pm$ 0.58 vs. 1.20 $\pm$ 0.26,  $p=0.002$ ). Therefore, we conducted further analyses to aid the clearness of the association between the potential factors and response rates.

Next, we conducted the binary logistic regression between potential factors and medication effectiveness based on univariate analysis results. With consideration of sex, age, and disease duration being correction factors, the results suggested that the



**Figure 2.** Proportion of patients achieving PASI 75 at week 4 in male or female patients. Male vs. female: 10.5% vs. 26.3%,  $p=0.047$ . (PASI 100: 100% reduction in Psoriasis Area and Severity Index).



**Figure 3.** Proportion of patients achieving PASI 75 at week 4 in groups with or without family history of psoriasis. With family history vs. without family history: 44.4% vs. 13.9%,  $p=0.044$ . (PASI 100: 100% reduction in Psoriasis Area and Severity Index).

possibility of achieving different treatment goals (PASI 75/90/100) after the first dose of ustekinumab went up along with the value of serum HDL-C level arose (expressed as adjusted odds ratio < 95% confidence interval>: PASI 75: 28.484<2.035-248.419>,  $p=0.011$ ; PASI 90: 28.226<2.828-281.729>,  $p=0.004$ ; PASI 100: 12.175<1.876-79.028>,  $p=0.009$ ) (Table 4).

### Safety

A total of 3(0.3%) patients reported adverse events (AEs) during the 4-week observation, which were skin pruritus ( $n=1$ ), elevated transaminase ( $n=1$ ) and eczema ( $n=1$ ) (Table 5). The patient with elevated transaminase tested at local hospital after the first-dose ustekinumab treatment was the only case leading to drug discontinuation in this study. No severe adverse event (SAE) was observed during this study.

### Discussion

MS has been reported to affect the long-term medication response of biologic therapy (9). However, few researches have validated the effect of MS on the short-term effectiveness of ustekinumab yet. Throughout this study, we aimed to observe and analyze real-world data on the short-term effectiveness of ustekinumab after the first dose. Firstly, within the four-week observation period, 30.5% of patients achieved the primary treatment goal (PASI 75) after receiving only the first-dose ustekinumab treatment (Table 2). Secondly, we found that sex, family history of psoriasis, MS, serum TG level, and serum HDL-C level were possible factors of short-term effectiveness (Tables 3 and 4). Further, when adjusted by sex, age, and disease duration, the possibility of achieving treatment goals (PASI 75/90/100) at week 4 increased along with serum HDL-C level arose.

Even though the confidence interval of HDL-C ratio is wide as mentioned above, which could be related to various reasons like the small sample size, the relatively short observation period, and ethnic factor, we still considered serum HDL-C level a potential predictor for the short-term effectiveness. Interestingly, Chau Yee Ng et al. found that after the 24-week observation period, the serum HDL-C level remained unchanged (25). The serum HDL-C level is susceptible to various factors, such as lifestyle, liver function, genetic factor et al. thus showing fluctuations (25–27). This present study found significant serum HDL-C level changes in the short-term, which might be a temporary phenomenon. Not only does HDL-C play a decisive role in the cholesterol reverse transportation, but it is also important in anti-inflammation process (28). Thus, from a long-term perspective, when the systemic utilization of adipose tissue tends to balance and the inflammation diminishes, the impact of ustekinumab on HDL may tend to

**Table 4.** Association between PASI 75 /90/100 response and baseline characteristics.

Characteristic	PASI 75				PASI 90				PASI 100			
	B	p	adjOR	95%CI	B	P	adjOR	95% CI	B	p	adjOR	95% CI
Sex	−0.133	0.824	0.875	0.270-2.836	0.774	0.248	2.169	0.583-8.067	1.499	0.051	4.478	0.997-20.116
Age	−0.005	0.828	0.995	0.953-1.039	0.006	0.804	1.006	0.959-1.056	0.030	0.281	1.030	0.976-1.088
Disease duration	−1.142	0.329	1.033	0.971-1.100	−0.011	0.764	0.989	0.922-1.061	−0.043	0.311	0.958	0.881-1.041
Family history of psoriasis	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A	1.664	0.068	5.282	0.884-31.561
Metabolic syndrome	−1.142	0.329	0.319	0.032-3.155	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
TG	−0.010	0.911	0.990	0.836-1.174	N/A	N/A	N/A	N/A	N/A	N/A	N/A	N/A
HDL-C	3.113	0.011	28.484	2.035-248.419	3.340	0.004	28.226	2.828-281.729	2.499	0.009	12.175	1.876-79.028

TG: triglyceride; HDL-C: high density lipoprotein cholesterol; adjOR: adjusted odds ratio; CI: confidence interval; N/A: not available, too small sample of the variable; P value <0.05 was considered statistically significant.



**Table 5.** Adverse events during the 4-week treatment period.

Adverse event	Patients (n=98)
Skin pruritus	1
Elevated transaminase	1
Eczema	1

flatten out, as the results shown in another 52-week observational study (29,30). Future studies might be necessary to find predicting factors responsible for metabolic parameter changes in Chinese psoriasis patients treated with ustekinumab.

In a network meta-analysis of various IL-12/23 biologics for the treatment of psoriasis, ustekinumab performed mediocre in terms of efficacy and tolerability (23). However, in this 4-week observational study, achievements were obtained both in skin lesion clearing and quality-of-life improvement. For skin lesion clearing, compared with the RCT data (31), the real-world data in this study showed more effective results in the medication response rates after the first-dose application (real-world data vs. RCT data: PASI 75: 30.5% vs. 20.6%; PASI 90: 18.9% vs. 5.4%; PASI 100: 16.8% vs. 0.9%). Nearly one-third of the patients in this study achieved the primary treatment goal (PASI 75) after only the first-dose ustekinumab treatment. And with the obvious reduction in PASI scores, 96.9% (95/98) of the patients chose to continue the subsequent treatments. Next, as for the quality of life, the mean value of DLQI dropped from 7.6 to 2.7 during the 4-week observation. In addition, DLQI 0/1 could be considered as having no effect on daily life (32). In this study, the percentage of patients achieving DLQI 1/0 increased nearly tenfold before and after the first-dose application (from 9.2% to 42.3%), which indicated that nearly half of the patients cast off the extra burden on daily life in the short-term. The achievement of the primary treatment goal and the improvement of the quality of life in the short-term may assist to raise the confidence and compliance of patients.

As regards factors associated with the short-term response, data in our research found that the response rates were higher in females and patients with a family history of psoriasis. Some studies have suggested that female gender may be associated with a decreased response to biologic therapies (33, 34). However, in an eight-year study on ustekinumab treatment in psoriasis, real-life experience results showed better effectiveness in female gender (35). Moreover, Delia et al’s research findings indicated that there was no obvious correlation between gender and effectiveness of biologic therapies (36). Moreover, Therefore, whether there is a significant correlation between gender and biologic therapy effectiveness still remains unclear. Reasons for these different results may be attributed to racial composition diversity and variations in geographical environments. Therefore, it may be the environmental and ethnic differences contributing to higher medication response in Chinese females of skin lesion clearance (PASI 100) in this study (female vs. male: 26.3% vs. 10.5%,  $p=0.044$ ). Also, regardless of the degrees of consanguinity therein, patients with a family history of psoriasis were more likely to achieve skin lesion clearance after the first-dose application (with family history vs. without family history: 44.4% vs. 13.9%,  $p=0.042$ ). It is validated that family history may be a risk factor for developing psoriasis (37–39), but temporarily few studies focused on the impact on medication response obtaining or maintaining, in which case further large-scale researches were needed.

In addition, metabolic parameters including MS, serum TG level, and serum HDL-C level were also displayed to affect the short-term effectiveness The appearance of MS and dyslipidemia are related to impaired pro-inflammatory cytokines, glucose metabolism, and

vascular endothelial biology (40,41). The abnormal lipid accumulation and impaired pharmacokinetic factors then caused chronic systemic inflammation, metabolic disorders, and impaired therapeutic response (42,43). However, by promoting cholesterol reverse transportation from macrophages (44), the special serum lipid parameter, HDL-C, is inversely associated with the risk of lipid dysregulation (45), which might help to explain the result that higher serum HDL level could improve and increase the possibility to achieve short-term effectiveness in this study. Consequently, putting the medical popular science education for psoriasis patients on a healthy lifestyle may assist to avoid developing MS and keep serum TG and HDL-C levels in the normal range. It may subsequently help to acquire better medication responses and raise their compliance with the subsequent treatments.

Our study has several potential limitations that may affect the interpretation of our findings. Firstly, although we focused on the short-term effectiveness of ustekinumab, the observation period of our study was only 4weeks, which may not completely rule out the possibility that some patients who did not achieve response in the short term could benefit from ustekinumab treatment in the long term. Secondly, the sample size of the study was relatively small, which may introduce bias in the results, and the lack of comparison with other treatment modalities limits a comprehensive evaluation of the advantages and disadvantages of ustekinumab in the treatment of psoriasis. Lastly, the study population consisted exclusively of individuals of Chinese ethnicity, therefore the generalizability of the findings to the wider global population may be limited.

Conclusion

Nearly one-third of patients achieved the primary treatment goal (PASI 75) after only the first-dose ustekinumab treatment. Sex, family history of psoriasis, metabolic syndrome, serum TG level, and serum HDL-C level may be associated with the short-term effectiveness. Furthermore, when adjusted by sex, age, and disease duration, the possibility to achieve different treatment goals (PASI 75/90/100) at week 4 went up along with the value of serum HDL-C level arose in this study, making serum HDL-C level a potential factor.

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Authors’ contribution

Xingyu Li and Xiaowen Xie performed the study design, data analysis, and manuscript writing. Jiashuai Li, Jingjin Hu, Minjia Tan, Jing Yang, Sichun Deng, and Yijie Liu contributed to the data collection and validation. Mi Zhang, Junchen Chen, Liqui Liao, Yehong Kuang, and Wu Zhu performed the diagnosis, sample collections, and/or manuscript revising. Yehong Kuang and Wu Zhu were clinic experts and gave suggestions for manuscript revision. All authors read and approved the final version of the manuscript.

Disclosure statement

The authors declare that the research was conducted in the absence of any commercial or financial relationships that could be construed as a potential conflict of interest.

## Statement of ethics

The principles outlined in the Declaration of Helsinki were followed in our research. This study was reviewed and approved by the institutional research ethics boards of Xiangya Hospital (approval number: 2018121106). Written informed consent was obtained from all of the adult participants and from parents/legal guardians of all participants under 18 years old.

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## Data availability Statement

All data generated or analyzed during this research are included in this article. Further requires can be directed to the corresponding authors.

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