

# A study of the efficacy and safety of plaque psoriasis treatment by TNF- $\alpha$ and IL-17A inhibitor biologics in patients who received the inactivated SARS-CoV-2 vaccine

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## Abstract

**ABSTRACT:** Background : Vaccination is an important method for the prevention of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission. There is currently a lack of real-world clinical data regarding the safety and efficacy of coronavirus disease 2019 (COVID- 19) vaccines with respect to plaque psoriasis treatment involving tumor necrosis factor (TNF)- $\alpha$  and interleukin (IL)- 17A inhibitors. Method s: We longitudinally analyzed 152 patients with plaque psoriasis, 86 of whom received two doses of inactivated COVID- 19 vaccine (either BBIBP-CorV or CoronaVac). Comparisons were made between patients undergoing treatment with biologics (TNF-  $\alpha$  inhibitors or IL- 17A inhibitors) or acitretin. Routine blood tests were used to assess safety; the psoriasis area and severity index (PASI) and dermatology life quality index (DLQI) were used to assess efficacy. Results: After inactivated COVID- 19 vaccination, biologics retained considerable advantages in terms of improving skin lesions (measured by PASI) and quality of life (measured by DLQI), compared with conventional treatment ( $p < 0.05$  and  $p < 0.01$ , respectively). Routine blood tests and hepatorenal function analyses suggested that inactivated SARS-CoV-2 vaccines did not alter the safety of biologics treatment ( $p > 0.05$ ). Conclusions: Inactivated SARS-CoV-2 vaccines do not have significant impacts on the safety and efficacy of biologics (TNF- $\alpha$  inhibitors or IL- 17A inhibitors) in patients with moderate to severe plaque psoriasis.

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# **A study of the efficacy and safety of plaque psoriasis treatment by TNF- $\alpha$ and IL-17A inhibitor biologics in patients who received the inactivated SARS-CoV-2 vaccine**

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## **Author's contribution statement**

YE Shuhong: writing-original draft (lead), Software (lead), formal analysis (lead); writing- review and editing (equal).

WU Jiawen: Project administration (lead), Conceptualization (lead), Methodology (lead).

SUN Hong: Methodology (lead), Conceptualization (supporting), formal analysis (equal).

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## **Conflict of interest**

All authors have no conflicts of interest. On behalf of all authors, the corresponding author states that there is no conflict of interest

## **Ethical approval and patient consent**

The Ethics Committee of The Second Affiliated Hospital of Xian Jiaotong University (Xibei Hospital) approved the study protocol. All participants provided informed consent for enrollment in the study.

## **ABSTRACT:**

**Background** : Vaccination is an important method for the prevention of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission. There is currently a lack of real-world clinical data regarding the safety and efficacy of coronavirus disease 2019 (COVID- 19) vaccines with respect to plaque psoriasis treatment involving tumor necrosis factor (TNF)- $\alpha$  and interleukin (IL)- 17A inhibitors.

**Method s**: We longitudinally analyzed 152 patients with plaque psoriasis, 86 of whom received two doses of inactivated COVID- 19 vaccine (either BBIBP-CorV or CoronaVac). Comparisons were made between patients undergoing treatment with biologics (TNF-  $\alpha$  inhibitors or IL- 17A inhibitors) or acitretin. Routine blood tests were used to assess safety; the psoriasis area and severity index (PASI) and dermatology life quality index (DLQI) were used to assess efficacy.

**Results**: After inactivated COVID- 19 vaccination, biologics retained considerable advantages in terms of improving skin lesions (measured by PASI) and quality of life (measured by DLQI), compared with conventional treatment ( $p < 0.05$  and  $p < 0.01$ , respectively). Routine blood tests and hepatorenal function analyses suggested that inactivated SARS-CoV-2 vaccines did not alter the safety of biologics treatment ( $p > 0.05$ ).

**Conclusions**: Inactivated SARS-CoV-2 vaccines do not have significant impacts on the safety and efficacy of biologics (TNF- $\alpha$  inhibitors or IL- 17A inhibitors) in patients with moderate to severe plaque psoriasis.

**Key words:** inactivated SARS-CoV-2 vaccine, psoriasis, biologics

## **1. Introduction**

Since 2019, the destructive effects of coronavirus disease 2019 (COVID-19) have rapidly spread around the globe. As of November 3, 2022, there were 640 million confirmed cases of COVID-19 worldwide<sup>1</sup>. The establishment of a safe and effective vaccine is an important component of efforts to prevent severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) transmission and subsequently achieve control of the pandemic.<sup>2</sup> Inactivated COVID-19 vaccines (e.g., BBIBP-CorV and CoronaVac) have entered phase III efficacy trials and are approved for emergency use in many countries.<sup>3,4</sup> However, COVID-19 vaccine hesitancy rates have reportedly reached 50% of the general population in some countries<sup>5</sup>.

Psoriasis is an immune-mediated inflammatory skin disease that affects approximately 125 million people worldwide<sup>6-8</sup>. The main treatments for moderate to severe plaque psoriasis are biologics, such as anti-interleukin (IL) 17 and anti-tumor necrosis factor (TNF)- $\alpha$ , as well as oral agents<sup>9, 10</sup>. Compared with nonbiologic systemic therapies, biologics usage has been associated with a lower risk of COVID-19-related hospitalization among patients with moderate to severe psoriasis.<sup>11</sup> Notably, COVID-19 vaccination has often been hindered by hesitancy based on false beliefs regarding the extension or prevalence of adverse events, potential flare-ups, and/or inefficient immunization among patients with psoriasis<sup>12</sup>. Discontinuing, not receiving systematic treatment or refusing COVID-19 vaccines are very detrimental to psoriasis, not only in physiological and psychological health, long-term benefits, also are bad for resistance to the COVID-19. Nonetheless, there are limited clinical data regarding the safety and efficacy of systemic psoriasis treatment after the administration of inactivated COVID-19 vaccines. Here, we investigated the impact of inactivated COVID-19 vaccine in patients with psoriasis who were undergoing treatment with biologics agents.

## **2. Materials and Methods**

### **2.1. Participants**

This longitudinal, retrospective, real-world clinical study included 152 patients (aged 18 to 67 years) who were clinically diagnosed with moderate to severe plaque psoriasis during the period from October 2020 to June 2022. Patients were excluded if they had hepatitis, tuberculosis, oncological diseases, and/or other systemic diseases; they were also excluded if they had already received COVID-19 vaccines. On the basis of systemic dermatological therapy, patients were divided into an acitretin group and a biologic (adalimumab or secukinumab) group. Eighty-six of the 152 patients received two doses of inactivated COVID-19 vaccine (either BBIBP-CorV or CoronaVac); these patients were regarded as the vaccinated group. All patients discontinued their psoriasis treatments for a period of time before and after each dose of vaccine.

### **2.2. Clinical protocol**

Patients in the acitretin group received acitretin 25 mg once daily, whereas patients in the biologic group received adalimumab 80 mg or secukinumab 300 mg every 4 weeks. Prior to observation, all patients underwent routine blood tests (neutrophil and lymphocyte counts) and hepatorenal function analyses (alanine aminotransferase, aspartate transaminase, serum total bilirubin, serum creatinine, and urea nitrogen levels). They were also assessed by a dermatologist to determine

their psoriasis area and severity index (PASI) and dermatology life quality index (DLQI) scores. Over the next 3 months, patients who received two doses of an inactivated COVID-19 vaccine (BBIBP-CorV or CoronaVac) were regarded as the vaccinated group (as noted above); the remaining patients were regarded as the unvaccinated group. The interval between the first and second doses was approximately 2 weeks. Routine blood tests and hepatorenal function analyses were conducted at 6 and 12 weeks after vaccination; all patients had received two doses of the inactivated vaccine by approximately 4 weeks after the first dose. The PASI and DLQI scores were also reassessed at 12 weeks after vaccination. Patients were asked to inform the research staff if they experienced any adverse events after vaccination, but their treatments could not be interrupted without consultation.

### **2.3 Evaluation scales and therapeutic agents**

The PASI was used to evaluate the severity of skin lesion and the DLQI was used to evaluate impacts on daily life<sup>13</sup>. Routine blood tests (as noted above) and hepatorenal function analyses (as noted above) were used to assess the safety of inactivated COVID-19 vaccines<sup>14-18</sup>. Adalimumab (40 mg) was manufactured by Zhejiang Hisun Pharmaceutical. Secukinumab (150 mg) was produced by Novartis Pharma Stein AG. Acitretin (25 mg per pill) was produced by Chongqing Huapont Pharm. CoronaVac (Sinovac Biotech) contained inactivated SARS-CoV-2 (3 µg per 0.5-mL dose); BBIBP-CorV (Sinopharm/Beijing Institute of Biological Products) contained inactivated SARS-CoV-2 (4 µg per 0.5-mL dose)<sup>19</sup>.

### **2.4 Statistical analysis**

Statistical analyses were conducted using SPSS software, version 26. Differences in primary outcomes among the three groups (acitretin and the two biologics subgroups) at weeks 0, 6 and, 12 were assessed by analysis of variance (MANOVA) with Bonferroni correction. P values < 0.05 were considered statistically significant.

## **3. Results**

### **3.1 Efficacy and safety of biologics treatment for patients with psoriasis after receipt of inactivated COVID-19 vaccine**

The biologics group exhibited better performance than the acitretin group in terms of improved PASI and DLQI scores ( $p < 0.01$ ) (Fig 1A, 1B); these scores did not significantly differ between the two biologics subgroups ( $p > 0.05$ ). Compared with the unvaccinated group, blood biochemistry and routine blood tests appeared unobvious discrepancy in the vaccinated group. Alanine aminotransferase was elevated in the acitretin group after vaccination ( $p < 0.05$ ) (Fig 1E), but routine blood tests and blood biochemistry did not reveal significant differences among the three groups (acitretin and the adalimumab and secukinumab subgroups) ( $p > 0.05$ ). Differences between the vaccinated and unvaccinated groups were not statistically significant ( $p > 0.05$ ).

Additionally, 10 patients experienced transient exacerbation of skin lesions after the first or second dose of inactivated vaccine, but they recovered without any change in treatment regimen. The most serious case involved a 48-year-old woman who was receiving adalimumab for psoriasis. Her first dose was BBIBP-CorV, whereas her second dose was CoronaVac. After the second dose, some erythema began to appear on her upper arm and rapidly spread across her chest and abdomen; however, she almost fully recovered after switching psoriasis treatment to secukinumab (Fig 2).

### **3.2 Enhanced efficacy and safety of biologics used for treatment of plaque psoriasis**

After 12 weeks of treatment, the adalimumab and secukinumab subgroups exhibited significantly better PASI and DLQI scores, compared with the acitretin group (PASI  $p < 0.05$ ,  $p < 0.01$ ; DLQI  $p < 0.05$ ,  $p < 0.01$ ). However, there were no significant differences in PASI or DLQI scores between the adalimumab and secukinumab subgroups (PASI  $p > 0.05$ ; DLQI  $p > 0.05$ ) (**Fig 3A, B**).

Continuous monitoring of blood biochemistry and routine blood test results before and during the 12 weeks of treatment revealed a significant increase in the alanine aminotransferase level in the acitretin group (**Fig 3E**) ( $p < 0.01$ ), but there were no significant differences between the two biologics subgroups ( $p > 0.05$ ). Other indicators of blood biochemistry and routine blood tests have no significant difference between three groups ( $p > 0.05$ ).

### **3.3 Distinct effects of each inactivated COVID- 19 vaccine on patients with psoriasis**

Patients were classified into three groups according to the inactivated COVID- 19 vaccine that they received: two doses of BBIBP-CorV, two doses of CoronaVac, or one dose of each (i.e., both vaccines). Longitudinal observation revealed no significant differences among the three groups in terms of PASI and DLQI scores, or the results of routine blood tests and blood biochemistry analyses ( $p > 0.05$ ) (**Fig 4**). Although more adverse events occurred in the both vaccines group than in the other two groups, the difference was not statistically significant ( $p > 0.05$ ). Compared with conventional treatment, there was no direct relationship between the use of biologics and the side effects of COVID- 19 vaccines ( $p > 0.05$ ).

## **4. Discussion**

In patients with plaque psoriasis who were treated with TNF- $\alpha$  and IL- 17A inhibitors, inactivated COVID- 19 vaccines did not alter the original therapeutic advantages of biologics treatment. Moreover, the vaccines did not alter the relative safety of biologics treatments in terms of hepatorenal function or blood test results, compared with acitretin. Finally, no serious adverse events occurred. Therefore, we conclude that inactivated COVID- 19 vaccines are safe and well-tolerated among patients with plaque psoriasis. Furthermore, there have no significant impact on adverse events, recovery of skin lesions and improvement of quality of life in psoriasis combined with systemic treatment and homologous inactivated COVID- 19 vaccine. In the acitretin group, alanine aminotransferase was elevated regardless of vaccination in some patients; some previous studies have shown that alanine aminotransferase levels are elevated after long-term administration of acitretin.<sup>20</sup> Therefore, we speculate that this elevation is a result of acitretin treatment, rather than a result of inactivated COVID- 19 vaccines.

Many studies have shown that biologics (e.g., TNF- $\alpha$  and IL- 17A inhibitors) offer considerable advantages in terms of improving psoriasis skin lesions, along with an acceptable profile<sup>21,22</sup>.

However, in the COVID- 19 pandemic era, vaccination is important for the prevention of severe COVID- 19. Flare-ups, malaise, myalgia, fever, and arthralgia have reportedly occurred after the receipt of the BNT162b2 mRNA SARS-CoV-2 vaccine among patients receiving topical treatment for plaque psoriasis.<sup>23-25</sup> A few studies have also demonstrated exacerbation of lesions after the receipt of mRNA and adenovirus SARS-CoV-2 vaccines among patients with psoriasis who are undergoing treatment with biologics.<sup>26-27</sup>

However, no serious adverse events occurred throughout our study, which may be related with the properties of inactivated virus vaccine itself and the comorbidities of the patients. Some clinical studies have confirmed the safety and good tolerability of inactivated vaccines; the overall rates of adverse events were very low, and no deaths were reported.<sup>28-30</sup> In the present study, 10 patients experienced transient exacerbation of skin lesions after the first or second dose of inactivated

vaccine, whereas three patients reported colds after vaccination, and one patient experienced dietary irritation after vaccination; other patients reported no specific effects. Transient exacerbation of inflammatory responses may be induced by infection, environmental stimuli, or psoriasis progression. However, no serious adverse events occurred; thus, we concluded that inactivated COVID- 19 vaccines have a good safety profile in patients with moderate to severe plaque psoriasis who are undergoing treatment with biologics. Further experiments and data are needed to characterize the mechanisms involving inactivated vaccines in immune inflammatory diseases and biologics treatment.

In general, inactivated vaccines are safe and well-tolerated among patients with psoriasis who are undergoing treatment with biologics. Our findings support the administration of inactivated COVID- 19 vaccines to patients with immune inflammatory diseases who are receiving biotherapy, thus contributing to the treatment of psoriasis and the management of COVID- 19.

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## Results

**Table 1** Demographic and clinical characteristics of the study participants .(n = 152)

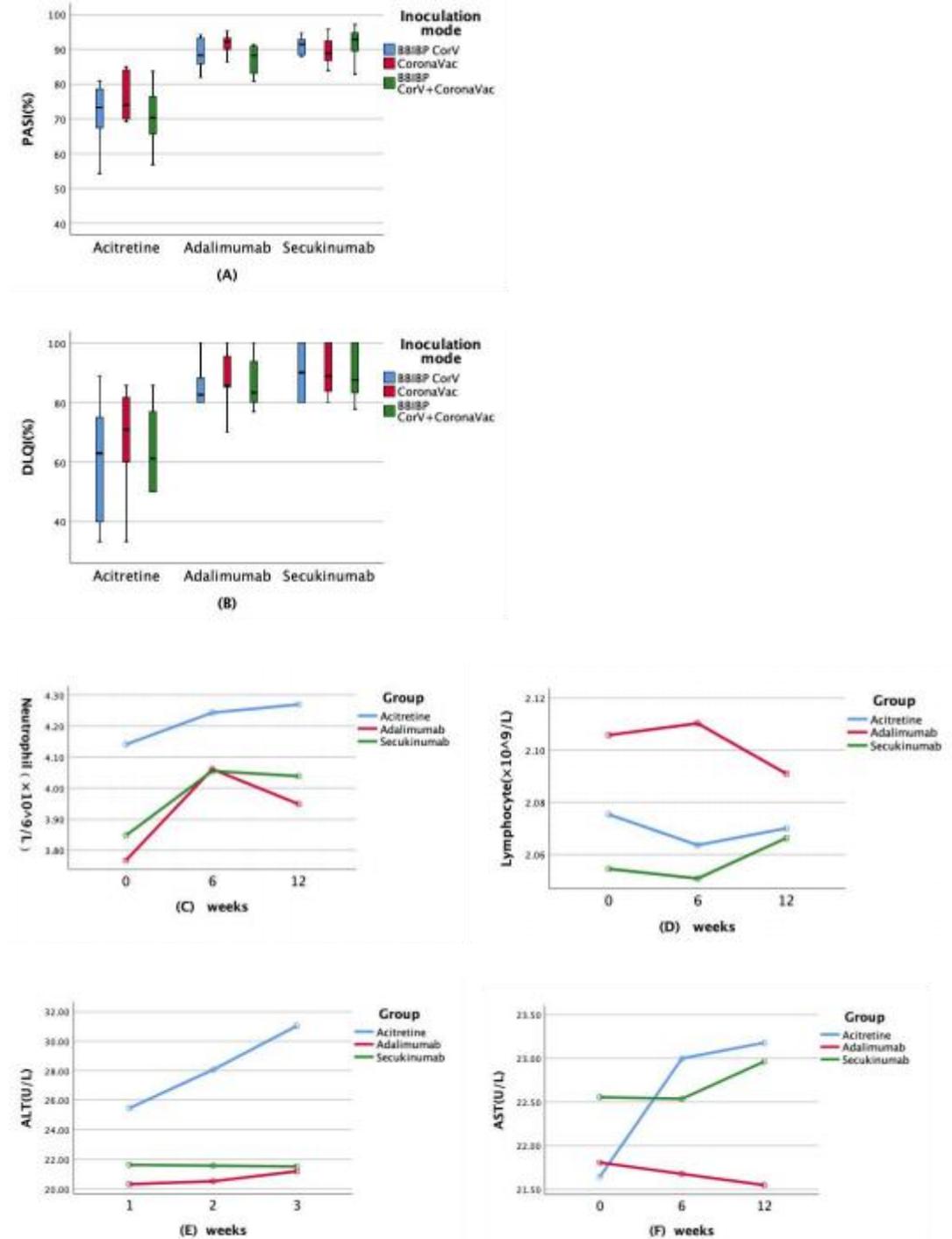
Characteristics		Adalimumab (n=51)		Secukinumab (n=48)		Acitretine (n=53)	
		Vac	Nonvac	Vac	Nonvac	Vac	Nonvac
Inactivated COVID19 vaccine							
Gender (n)	M	10	8	8	10	8	9
	F	21	12	19	11	20	16
Age of the average (min to max)		38.35 (19-70)	40.20 (18-60)	34.33 (19-60)	36.95 (18-65)	38.07 (20-63)	41.84 (19-67)

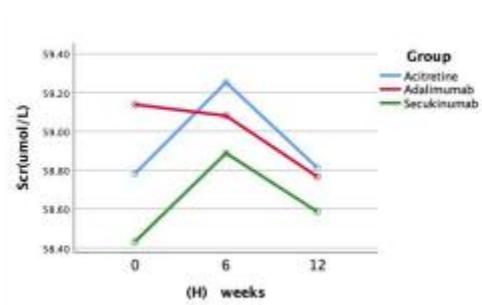
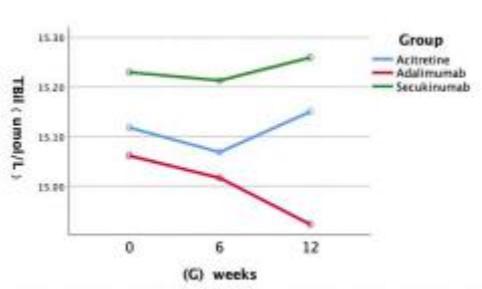
Vac vaccinated, Nonvac Nonvaccinated, M Male, F Female

**Table 2** Adverse event analysis of special concern after getting inactivated COVID- 19 vaccine within 12 weeks.

Adverse event n (%)	Acitretine ( n=53)	Adalimumab ( n=51)	Secukinumab ( n=48)
Severe infection	0	0	0
Opportunistic infection	0	0	0
Herpes zoster	0	0	0
Malignant tumor	0	0	0
Abnormal liver function	3	0	0
Abnormal renal function	0	0	0
Dermatoma	0	0	0
Cardiovascular event	0	0	0
Hematological Disease	0	0	0
Anaphylaxis need epinephrine	0	0	0

**Fig1 . Efficacy and safety of biologics treatment for patients with psoriasis after receipt of inactivated COVID-19 vaccine**





Patients have finished the first dose and second dose COVID- 19 inactivated vaccine in the course of 12 weeks. A and B shows the therapeutic effect after vaccinated, C-H shows aspartate transaminase (AST), alanine aminotransferase (ALT), Neutrophil, Lymphocyte, total bilirubin (TBil) and serum creatinine (SCr) at certain days before and after 12 weeks of systematic therapy, adalimumab and secukinumab groups exhibit significant difference compared with acitretine group in increasing PASI and DLQI ( $p < 0.01$ ,  $p < 0.01$ ). There was no significant difference between groups in other safety measures except ALT, ALT still shows an increase in acitretine group after vaccination ( $P < 0.05$ ) (E).

**Fig 2**

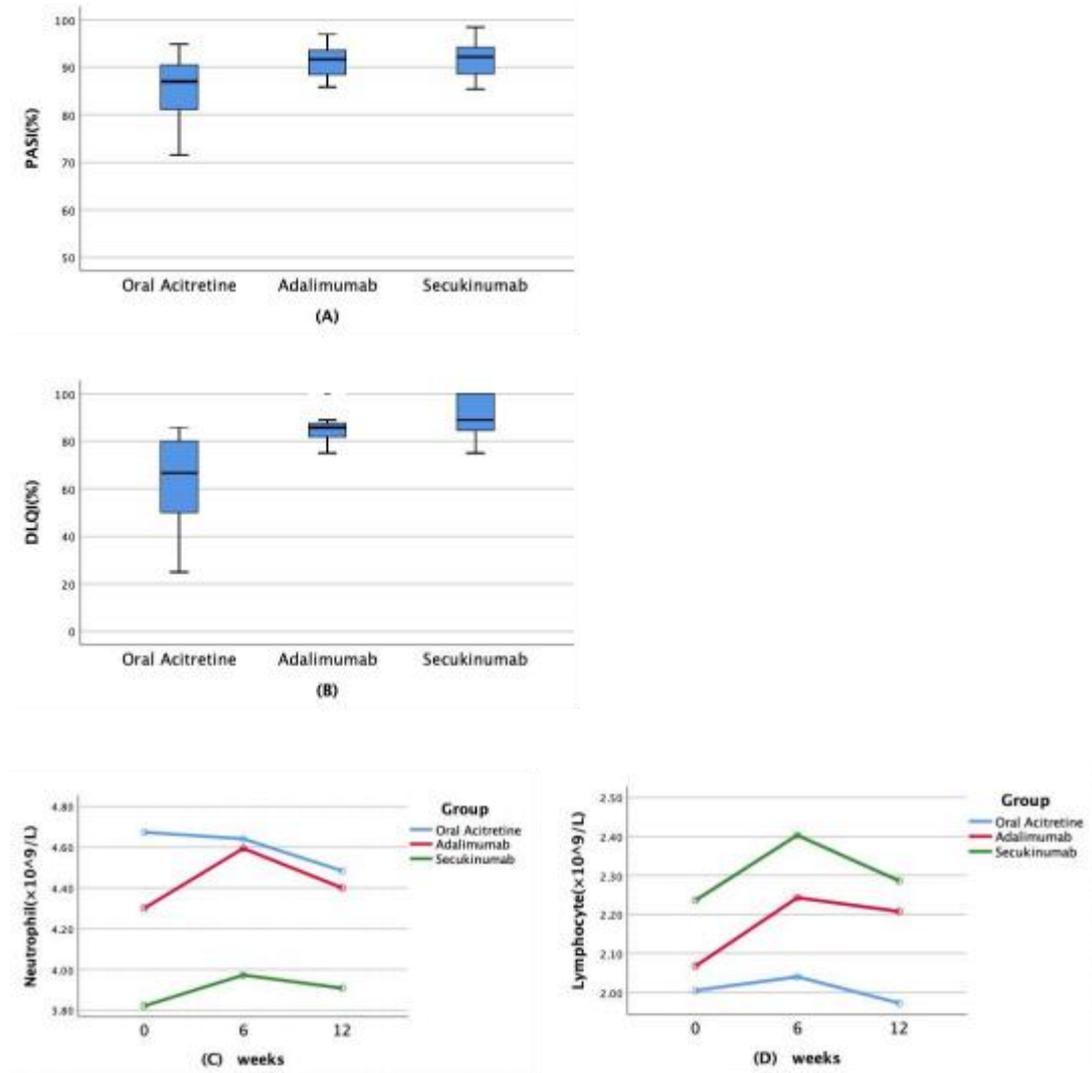


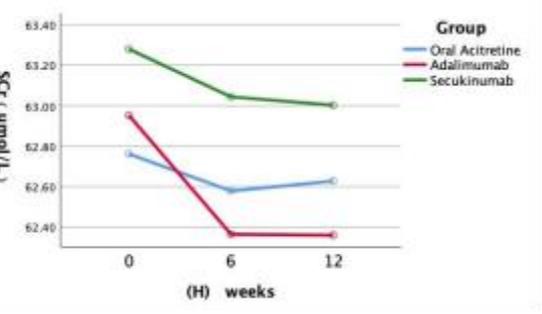
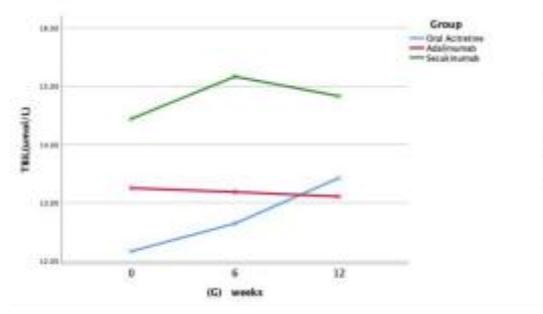
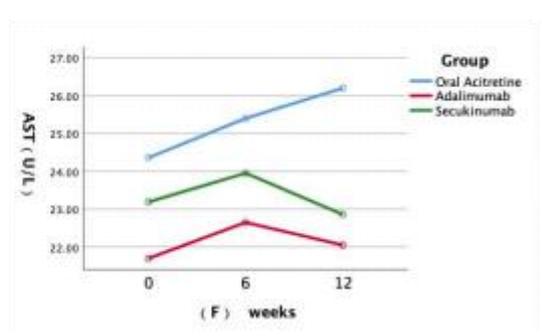
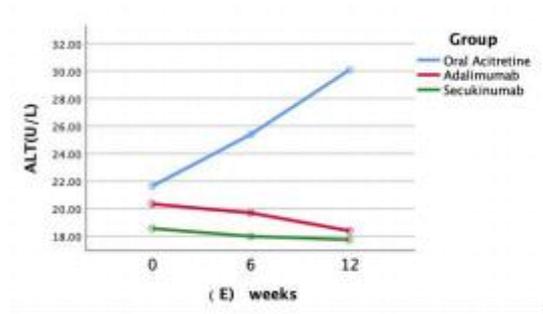
before

after

A 38-years-old man who regularly received adalimumab 80 mg every 4 weeks for his psoriasis showed no progression of psoriasis after the first dose of BBIBP CorV, after received the second dose of CoronaVac, he had erythematous lesions gradually increased, he reported a mild cough and sore throat before getting his second vaccine. Without interruption of his adalimumab or systematic use of glucocorticoids, his lesions gradually recovered after 12 weeks.

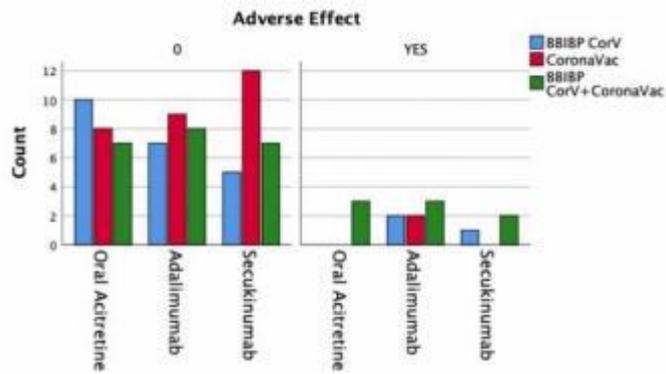
**Fig3 Enhanced efficacy and safety of biologics used for treatment of plaque psoriasis**





Participants have not received any COVID-19 vaccine, and B shows the therapeutic effect after 12 weeks, adalimumab and secukinumab groups exhibit a distinct strength in improving PASI and DLQI than acitretine ( $p < 0.05$ ,  $p < 0.05$ ), there was a significant increase in the level of alanine transaminase ( $p < 0.01$ ) (E). There was no significant difference between groups in other safety measures ( $P > 0.05$ ).

**Fig4 Distinct effects of each inactivated COVID-19 vaccine on patients with psoriasis**



Numbers of people with or without adverse reactions is shown in the graph, patients are vaccinated in three ways, two dose with BBIBP-CorV group, two dose with CoronaVac group and have both vaccines administered. three groups showed no significant differences in PASI, DLQI ( $p > 0.05$ ).