ORIGINAL RESEARCH

Clinical study on the treatment of psoriasis (liver depression and blood heat type) with Tianqi Qingyin decoction

Bin Zhou[1], Yin Xue[2,*]

1. Department of Dermatological, Changzhou Wujin People's Hospital, Tianning District, Changzhou, Jiangsu, 213100, China.
2. Department of TCM, Changzhou Wujin People's Hospital, Tianning District, Changzhou, Jiangsu, 213100, China.

*** Corresponding Author:Yin Xue**; E-mail: xueyin861101@163.com

Abstract

Objective

To probe the effect of Tianqi Qingyin decoction on psoriasis (liver depression and blood heat type).

Methods

From January 2021 to April 2022, 80 patients treated in our hospital were collected and randomly separated into study group (SG) and control group (CG), each group had 40 cases. The CG was given compound Qingdai Capsule. The SG was given Tianqi Qingyin decoction. The clinical effect, PASI scores, cytokine IL-17 and TNF-α contents, DLQI scores and occurrence of adverse reactions in both groups were compared.

Results

The total effective rate in the SG was elevated relative to the CG ($\chi 2=6.28$, $P<0.05$). No difference was seen in PASI scores, cytokine IL-17 and TNF-α contents and DLQI scores between both groups previous to treatment ($P>0.05$). After treatment, all above indexes were declined in both groups, and those of the SG were lessened relative to the CG ($P<0.05$). The occurrence of adverse reactions in the SG was reduced in comparison with the CG ($P<0.05$).

Conclusion

Tianqi Qingyin decoction can promote clinical efficacy in treating liver depression and blood heat type psoriasis and is worthy of further clinical application.

Keywords: Tianqi Qingyin decoction, psoriasis, liver depression and blood heat type, IL-17, TNF-α.

Introduction

Psoriasis belongs to a chronic inflammatory skin disease, which can be divided into four types, containing psoriasis vulgaris, psoriasis arthropathy, pustular psoriasis along with erythrodermic psoriasis, and psoriasis vulgaris is a common and frequently occurring clinical type[1]. The pathogenesis of psoriasis is complex, which is closely related to genetic immunity and mental environment[2]. With the development of social economy along with the change of lifestyle, the incidence of psoriasis tends to be high[3]. Psoriasis is manifested as a destructive rash, which not only has a long treatment cycle, great economic loss, and unsatisfactory clinical efficacy, but also causes certain mental and psychological disorders to patients with repeated illness[4]. At the same time, it will also have an adverse influence on the quality of life of patients, resulting in a vicious cycle[5].

Due to the unknown etiology and complex pathogenesis underlying this disease, there are no good prevention and treatment methods at present. Immunosuppressants, glucocorticoids, retinoids, and antibiotics are the main treatment methods[6]. However, due to the large side effects and uncertain efficacy, the clinical application of these drugs is limited[7]. Traditional Chinese medicine (TCM) has been widely applied in clinic because of its definite effect and few side effects in treating psoriasis[8]. At present, the principle of TCM in the treatment of this disease is dialectical treatment, combination of internal and external treatment, and most of them are used from the perspective of blood heat, blood dryness, along with blood stasis, and the treatment is carried out by cold blood, blood nourishment, blood vitality, and other treatment methods[9].

Herein, we explored the effect of TCM of Tianqi Qingyin decoction on on the treatment of psoriasis (liver depression and blood heat type).

Data and methods

General data

From January 2021 to April 2022, a total of 80 patients treated in our hospital were included in this study. To ensure the reliability and objectivity of the group allocation, a rigorous randomization process was implemented.

First, all eligible patients were numbered sequentially from 1 to 80 according to the order of their admission. Then, a computer - generated random number sequence was created using a well-established statistical software. The random number sequence consisted of 80 distinct random numbers, each corresponding to one of the numbered patients.

Next, these random numbers were sorted in ascending order. The first 40 patients in the sorted list were assigned to the study group (SG), and the remaining 40 patients were assigned to the control group (CG).

To further enhance the blinding and prevent selection bias during the group assignment process, we used sealed envelopes. Each patient's assigned group information was written on a piece of paper and placed inside an opaque, sealed envelope. The envelopes were then shuffled thoroughly to ensure randomness. When a patient was ready to be assigned to a group, an envelope was randomly selected and opened by an independent researcher who was not involved in the patient recruitment or subsequent data collection and analysis. This researcher then informed the clinical staff of the patient's group assignment.

The SG had 22 men and 18 women, aged from 18 to 58 years, the average age was (33.64±3.42) years. The course of disease ranged from 2 to 18 years, with an average of (6.95±2.36) years. There were 30 patients in progressive phase and 10 patients in static phase. The SG had 23 men and 17 women, aged from 19 to 57 years, the average age was (33.42±3.35) years. The course of disease ranged from 3 to 19 years, with an average of (6.92±2.43) years. There were 32 patients in progressive phase and 8 patients in static phase. No differences were seen in gender, age, course of disease, and stage between both groups (P>0.05), reflecting comparable.

Diagnostic criteria

Diagnostic criteria of western medicine of psoriasis vulgaris: most acute onset, the initial skin lesions are red papules or maculopapular rashes, gradually expanding into clear red plaques, which can be in a variety of forms (such as guttate, plaque, coin, map, and shell), covered with a thick layer of silvery-white scales, scraped with film phenomenon and spotted hemorrhage.

The syndrome differentiation criteria of TCM for liver depression and blood heat syndrome: The rash is mostly spotty and develops rapidly, with bright red color, layers of scales, intense itching, spot-like bleeding, dry mouth, sore throat, irritability, dry stool, yellow urine, red tongue, thin yellow coating, along with slippery or slippery pulse strings.

Inclusion criteria

(1) Accord with the above diagnostic criteria for psoriasis vulgaris. (2) TCM syndrome differentiation was liver depression and blood heat syndrome. (3) Had not received hormone, photochemotherapy, immunosuppressive therapy and other treatments within half a year. (4) Patients who voluntarily participated and signed informed consent.

Exclusion criteria

(1) Pregnant or lactating women. (2) Had received hormonal, photochemotherapy, immunosuppressive and other treatments within six months. (3) Patients with cardiovascular and cerebrovascular diseases, hyperlipidemia, abnormal liver and kidney function or mental diseases. (4) Those who were allergic to the drug in this study; (5) Patients who could not obey the doctor's suggestion for treatment and affect the evaluation of efficacy.

Methods

The CG was given compound Qingdai Capsule (produced by Shaanxi Tianning Pharmaceutical Co., LTD), 4 capsules each time, three times per day.

The SG was given Tianqi Qingyin decoction orally.

Pharmaceutical composition: Tianqi powder 6 g (decoction), Rehmannia 15 g, radix Scrophulariae 15 g, Radix Ophiopogonis 12 g, Salvia Miltiorrhiza 15 g, Coptis Chinensis 9 g, Honeysuckle 15 g, Bamboo Leaf Heart 3 g, Radix Pseudostellariae 12 g, Rhizoma Smilacis Glabrae 30 g, Cortex Dictamni 12 g, Plaster 30 g (decocted first).

To ensure the quality and reproducibility of the study, all the herbs used in the Tianqi Qingyin decoction were obtained from reputable suppliers with strict quality-control measures. Each batch of herbs was accompanied by a detailed quality-control report that included information such as the batch number, the source of the herbs, and the results of quality-control tests. These tests typically included checks for the presence of contaminants (such as heavy metals, pesticides, and aflatoxins), as well as the determination of the content of active ingredients.

One dose of 150 mL was taken for decoction in water, twice a day.

Both groups were treated with 1 month as a course of treatment, and the efficacy was determined followed by 2 courses of treatment. No other drugs were used during the observation period, and the improvement of rash was observed regularly every week.

Observation indexes

(1) Psoriasis area and Severity index (PASI) score [10]: Evaluation area (A): The four body parts were scored on a scale of 0 to 6. Area: 0 points without rash; <10% was 1 score, 10%-29% was 2 points, 30%-49% was 3 points, 50% to 69% were 4 points, 70%-89% were 5 points, 90%-100% was 6 points. Body parts of the area such as below: head 10%, torso 30%, upper extremity 20%, and lower limb 40%. Evaluation of clinical severity: erythema (E), infiltration (I), and scale (D). Each characteristic was evaluated by 0-4 points according to no, mild, moderate, severe along with extremely severe. The formula calculated the score of each body part, and then accumulated to get the total score, which was 0-72 points. Formula: PASI score = (Ehead + Ihead+ Dhead) × Ahead × 0.1+ (Eupper limb + Iupper limb + Dupper limb) × Aupper limb × 0.2 + (Ebody + Ibody + Dbody) × Abody × 0.3 + (Elower limb + Ilower limb + Dlower limb) × 0.4.

(2) Therapeutic evaluation: Efficacy index was calculated according to the total score obtained by PASI score: Efficacy index (%) = (total score before treatment - total score after treatment)/total score before treatment ×100%. Clinical recovery: skin lesions subsided, no obvious clinical symptoms, efficacy index ≥90%. Obvious effect: most of the skin lesions subsided, clinical symptoms improved significantly, and the efficacy index was 60%-89%. Effective: partial skin lesions subsided, clinical symptoms were slightly improved, and the efficacy index was 20%-59%. Ineffective: no loss of skin, no improvement or aggravation of clinical symptoms, efficacy index <20%. The total effective rate was the percentage of total cases of recovery and apparent effect.

(3) Cytokine detection: 3 mL of blood was gathered from the subject's elbow vein. After standing at room temperature, the supernatant was taken after centrifugation. The contents of serum cytokines interleukin-17 (IL-17) along with tumor necrosis factor-α (TNF-α) were quantitatively analyzed by ELISA.

(4) Quality of life: Dermatology Life Quality Index (DLQI) was implemented to measure the quality of life of psoriasis patients[11].

(5) The occurrence of adverse reactions containing dry mouth, dry eyes, and pruritus were recorded in both groups.

https://dx.doi.org/10.4314/mmj.v37i5.6

These were monitored through a combination of self-reporting by patients and physician observation. Patients were instructed to report any occurrence of these symptoms during the treatment course, and physicians conducted regular skin and general physical examinations to note any relevant signs.

Statistical analysis

The clinical data were statistically processed by SPSS Statistics 20.0. The measurement data were represented by x-±s and count data were exhibited by rate (%). t test and $\chi 2$ test were implemented for comparison in both groups. P<0.05 was significant.

Results

Clinical effect in both groups

The total effective rate in the SG was 95.00%, which was elevated relative to 75.00% in the CG ($\chi 2$=6.28, P<0.05, Figure 1).

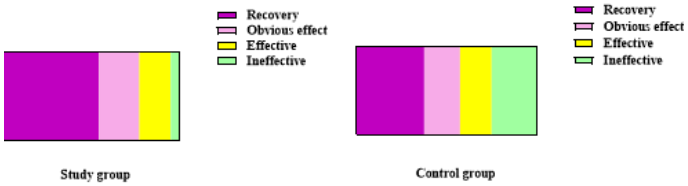

Figure 1 Clinical effect in both groups

PASI scores in both groups

No difference was seen in PASI scores between both groups previous to treatment (P>0.05). After treatment, PASI scores were declined in both groups, and those of the SG were lessened relative to the CG (P<0.05), as displayed in Figure 2

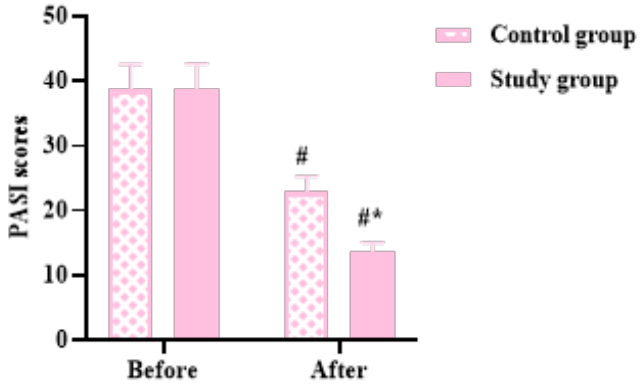

Figure 2 PASI scores in both groups.

#P<0.05, compared to before treatment, *P<0.05, compared to the control group.

Cytokine IL-17 and TNF-α contents in both groups

No difference was seen in IL-17 along with TNF-α contents between both groups previous to treatment (P>0.05). After treatment, IL-17 along with TNF-α contents in both groups were lessened in both groups, and those of the SG were decreased in comparison with the CG (P<0.05), as displayed in Figure 3.

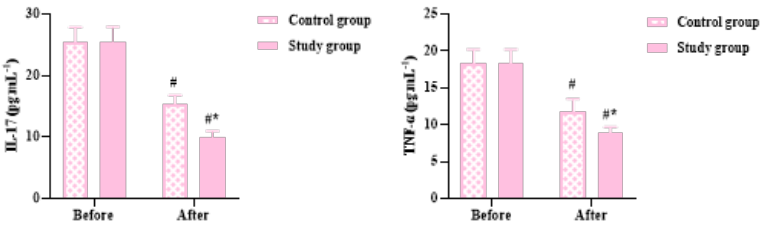

Figure 3 Cytokine IL-17 and TNF-α contents in both groups.

#P<0.05, compared to before treatment, *P<0.05, compared to the control group

DLQI scores in both groups

No difference was seen in DLQI scores between both groups previous to treatment (P>0.05). After treatment, DLQI scores were declined in both groups, and that of the SG were lower in comparison with the CG (P<0.05), as displayed in Figure 4.

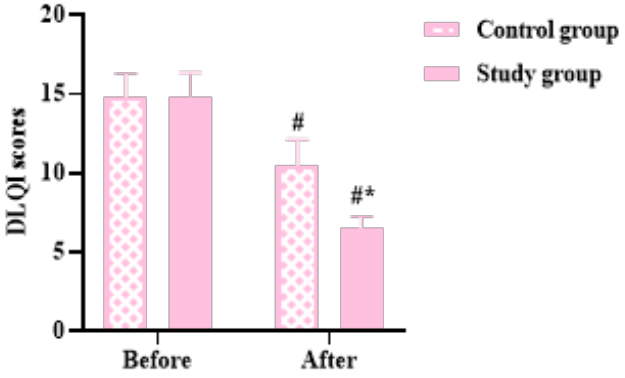

Figure 4 DLQI scores in both groups. #P<0.05, compared to before treatment

*P<0.05, compared to the control group

Occurrence of adverse reactions in both groups

The occurrence of adverse reactions in the SG was declined relative to the CG (P<0.05, Table 1).

Table 1 Occurrence of adverse reactions in both groups (n, %)

Groups	Dry mouth	Dry eyes	Pruritus	Total incidence rate (%)
Control group (n=40)	4	3	3	10 (25.00%)
Study group (n=40)	1	1	0	2 (5.00%)
χ^2	6.28			
P	<0.05			

Discussion

Psoriasis belongs to a frequent chronic inflammatory skin disease, accompanied with a long course of disease, repeated attacks, more difficult to treat[12]. Patients present with scaly, erythema and other symptoms, with a high incidence in winter, which directly influences the quality of life of patients[13]. From the theory of TCM, psoriasis patients are mostly of the liver depression and blood heat type, and mainly in the progressive phase. The rash occurrence and development are rapid, with an increasing number of new rashes[14]. In addition, the occurrence of liver depression and blood heat type psoriasis is related to a variety of factors, such as internal injury of emotions and poor circulation of qi and

blood, leading to heart fire hyperactivity, or external wind evil and mixed with dryness-heat in the skin, causing disease, or spleen and stomach disharmony caused by improper diet[15]. In addition to controlling the disease and reducing skin lesions, clinical treatment of this disease should also pay attention to the differentiation and treatment of TCM[16].

Tianqi Qingyin decoction is based on Tianqi, Rehmannia, radix Scrophulariae, Radix Ophiopogonis, Salvia Miltiorrhiza, Coptis Chinensis, Honeysuckle, Bamboo Leaf Heart, Radix Pseudostellariae, Rhizoma Smilacis Glabrae, Cortex Dictamni, and Plaster. Rhmannia is designed to clear heat, cool blood and accelerate blood circulation. Tianqi can accelerate blood circulation as well as remove blood stasis. Salvia Miltiorrhiza can clear the heart, cool the blood, and activate the blood. Radix Scrophulariae and Radix Ophiopogonis can nourish Yin and promote fluid production. Coptis Chinensis, Honeysuckle, Rhizoma Smilacis Glabrae, Cortex Dictamni, and Gypsum have the function of clearing heat and detoxifying dampness, Radix Pseudostellariae can nourish qi and Yin, and Bamboo Leaf Heart can clear heart diuresis, allowing dampness and heat to be removed from the urine. Overall, Tianqi Qingyin decoction can clear heat and cool blood, detoxify, accelerate blood circulation, remove blood stasis, and nourish Yin and promote fluid production.

The results of this study revealed that, compared with the CG, the SG had higher total effective rate, higher PASI and DLQI scores, and lower incidence of adverse reactions. These results suggested that the clinical efficacy of Tianqi Qingyin decoction was effective, which could reduce the area of skin lesions, relieve skin itching, decrease adverse reactions, and promote the quality of life of patients.

Besides, the pathogenesis of psoriasis is a systemic immune response[17]. It has been found that Th17 cells together with related cytokines are implicated in the pathogenesis of psoriasis[18]. Th17 cells participate in immune regulation through secreting cytokines containing IL-17 and TNF-α[19]. Among them, IL-17 is the main effector, which plays a role by promoting the inflammatory response of the body, and can promote the secretion of multiple pro-inflammatory mediators containing IL-6, IL-21, along with IL-8[20]. TNF-α is mainly involved in immune response and is the main inflammatory mediators in psoriasis[21]. It has been reported that IL-17 and TNF-α levels are higher in psoriasis patients than normal people, which are involved in the early inflammatory response of psoriasis[22]. In this study, the serum levels of IL-17 and TNF-α were also decreased with the relief of clinical symptoms after treatment, further confirming that these inflammatory factors are involved in the pathogenesis of liver depression and blood heat type psoriasis[23]. Regarding the mechanism by which Tianqi Qingyin decoction lowers IL-17 and TNF-α levels, several herbal components in the decoction likely contribute through anti-inflammatory and immune-modulating effects. For instance, Coptis Chinensis contains berberine, which has been shown in previous studies to have anti-inflammatory properties[24]. Berberine can inhibit the activation of nuclear factor-κB (NF-κB), a key transcription factor involved in the production of various inflammatory cytokines, including IL-17 and TNF-α. By blocking NF-κB activation, berberine reduces the transcription and subsequent secretion of these cytokines, thereby alleviating the inflammatory response[25]. Salvia Miltiorrhiza is rich in tanshinones, which also possess anti-inflammatory and immune regulating activities[26]. Tanshinones can modulate the function of immune cells, such as macrophages and T cells[27]. They can inhibit the production of pro-inflammatory cytokines by macrophages and regulate the differentiation and function of T cell subsets, including Th17 cells. This regulation helps to reduce the secretion of IL-17 and other inflammatory cytokines, contributing to the overall anti-inflammatory effect of the decoction[28]. Rehmannia, with its ability to clear heat and cool blood, may also play a role in immune regulation. It can adjust the body's internal environment, balance the yin and yang, and thus influence the immune system[29]. Some components in Rehmannia may interact with immune cell receptors or signaling pathways, inhibiting the over-activation of immune responses and reducing the production of inflammatory cytokines[30].

In conclusion, Tianqi Qingyin decoction can significantly improve clinical efficacy in the treatment of liver depression and blood heat type psoriasis. The herbal components in the decoction likely work through anti-inflammatory and immune-modulating mechanisms to lower IL-17 and TNF-α levels, which is worthy of further clinical application.

References

1.Griffiths, C.E. and J.N. Barker, Pathogenesis and clinical features of psoriasis. Lancet, 2007. 370(9583): p. 263-271.

2.Rendon, A. and K. Schäkel, Psoriasis Pathogenesis and Treatment. Int J Mol Sci, 2019. 20(6).

3.Griffiths, C.E.M., et al., Psoriasis. Lancet, 2021. 397(10281): p. 1301-1315.

4.Langley, R.G., G.G. Krueger, and C.E. Griffiths, Psoriasis: epidemiology, clinical features, and quality of life. Ann Rheum Dis, 2005. 64 Suppl 2(Suppl 2): p. ii18-23; discussion ii24-5.

5.Boehncke, W.H. and M.P. Schön, Psoriasis. Lancet, 2015. 386(9997): p. 983-94.

6.Armstrong, A.W. and C. Read, Pathophysiology, Clinical Presentation, and Treatment of Psoriasis: A Review. Jama, 2020. 323(19): p. 1945-1960.

7.Tokuyama, M. and T. Mabuchi, New Treatment Addressing the Pathogenesis of Psoriasis. Int J Mol Sci, 2020. 21(20).

8.Xu, M., et al., In-depth serum proteomics reveals biomarkers of psoriasis severity and response to traditional Chinese medicine. Theranostics, 2019. 9(9): p. 2475-2488.

9.Meng, S., et al., Psoriasis therapy by Chinese medicine and modern agents. Chin Med, 2018. 13: p. 16.

10.Gooderham, M., et al., Long-term, durable, absolute Psoriasis Area and Severity Index and health-related quality of life improvements with risankizumab treatment: a post hoc integrated analysis of patients with moderate-to-severe plaque psoriasis. J Eur Acad Dermatol Venereol, 2022. 36(6): p. 855-865.

11.Mattei, P.L., K.C. Corey, and A.B. Kimball, Psoriasis Area Severity Index (PASI) and the Dermatology Life Quality Index (DLQI): the correlation between disease severity and psychological burden in patients treated with biological therapies. J Eur Acad Dermatol Venereol, 2014. 28(3): p. 333-7.

12.Korman, N.J., Management of psoriasis as a systemic disease: what is the evidence? Br J Dermatol, 2020. 182(4): p. 840-848.

13.Oji, V. and T.A. Luger, The skin in psoriasis: assessment and challenges. Clin Exp Rheumatol, 2015. 33(5 Suppl 93): p. S14-9.

14.Wu, M., et al., The Immunoregulatory Effects of Traditional Chinese Medicine on Psoriasis via its Action on Interleukin: Advances and Considerations. Am J Chin Med, 2018. 46(4): p. 739-750.

15.Li, T., et al., Potential effects and mechanisms of Chinese herbal medicine in the treatment of psoriasis. J Ethnopharmacol, 2022. 294: p. 115275.

16.Dai, D., et al., Evidence and potential mechanisms of traditional Chinese medicine for the treatment of psoriasis vulgaris: a systematic review and meta-analysis. J Dermatolog Treat, 2022. 33(2): p. 671-681.

17.Zhang, B., et al., Single-cell profiles reveal distinctive immune response in atopic dermatitis in contrast to psoriasis. Allergy, 2023. 78(2): p. 439-453.

18.Li, B., et al., The role of Th17 cells in psoriasis. Immunol Res, 2020. 68(5): p. 296-309.

19.De Simone, V., et al., Th17-type cytokines, IL-6 and TNF-α synergistically activate STAT3 and NF-kB to promote colorectal cancer cell growth. Oncogene, 2015. 34(27): p. 3493-503.

20.Miossec, P. and J.K. Kolls, Targeting IL-17 and TH17 cells in chronic inflammation. Nat Rev Drug Discov, 2012. 11(10): p. 763-76.

21.Lian, N., L. Zhang, and M. Chen, Tumor necrosis factors-α inhibition-induced paradoxical psoriasis: A case series and literature review. Dermatol Ther, 2020. 33(6): p. e14225.

22.Krueger, J.G., et al., IL-17A is essential for cell activation and inflammatory gene circuits in subjects with psoriasis. J Allergy Clin Immunol, 2012. 130(1): p. 145-54.e9.

23.Xie, W., et al., Incidence of and Risk Factors for Paradoxical Psoriasis or Psoriasiform Lesions in Inflammatory Bowel Disease Patients Receiving Anti-TNF Therapy: Systematic Review With Meta-Analysis. Front Immunol, 2022. 13: p. 847160.

24.Zhang, S., et al., Acetylation of p65(Lys310) by p300 in macrophages mediates anti-inflammatory property of berberine. Redox Biol, 2023. 62: p. 102704.

25.Wang, K., et al., Inhibition of inflammation by berberine: Molecular mechanism and network pharmacology analysis. Phytomedicine, 2024. 128: p. 155258.

26.Gao, H., et al., Total tanshinones exhibits anti-inflammatory effects through blocking TLR4 dimerization via the MyD88 pathway. Cell Death Dis, 2017. 8(8): p. e3004.

27.Ma, S., et al., Evaluation of the anti-inflammatory activities of tanshinones isolated from Salvia miltiorrhiza var. alba roots in THP-1 macrophages. J Ethnopharmacol, 2016. 188: p. 193-9.

28.Liu, M., Effect of crosstalk between Th17 and Th9 cells on the activation of dermal vascular smooth muscle cells in systemic scleroderma and regulation of tanshinone IIA. An Bras Dermatol, 2022. 97(6): p. 716-728.

29.Huang, Y., et al., Enhancing protective immunity against bacterial infection via coating nano-Rehmannia glutinosa polysaccharide with outer membrane vesicles. J Extracell Vesicles, 2024. 13(9): p. e12514.

30.Zhang, W., et al., Effects of Rehmanniae Radix Praeparata polysaccharides on LPS-induced immune activation in mice based on gut microbiota, metabolomics and transcriptomics. Int J Biol Macromol, 2025. 311(Pt 3): p. 143981.