DOI: 10.53469/jcmp.2025.07(04).37

Clinical Efficacy Observation of Integrated Traditional Chinese and Western Medicine Therapy in the Treatment of Acne Vulgaris

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Abstract: ***Objective:*** ***To observe the clinical efficacy and safety of traditional Chinese medicine (TCM) decoction combined with clindamycin phosphate gel in the treatment of acne vulgaris.*** ***Methods:*** ***A total of 70 patients with acne vulgaris were randomly divided into an observation group (n=35) and a control group (n=35) following a randomized, controlled, single-blind design. The control group received topical clindamycin phosphate gel, while the observation group was additionally treated with oral TCM decoction. The treatment duration was 7 days per course, with a total of 28 days for both groups. Clinical efficacy and adverse reactions were recorded at 14 and 28 days of treatment.*** ***Results:*** ***After four treatment courses, the overall effective rate and cure rate in the observation group were significantly higher than those in the control group.*** ***Conclusion:*** ***The combination of TCM and Western medicine can further improve therapeutic outcomes in acne vulgaris and is worthy of clinical promotion.***

Keywords: Integrated traditional Chinese and Western medicine, Acne vulgaris, Clinical efficacy observation.

1. Introduction

Acne vulgaris, a prevalent chronic inflammatory dermatological disorder, predominantly affects the facial (cheeks and forehead) and upper trunk (chest, back, and shoulders) regions, typically exhibiting symmetrical distribution patterns. The initial presentation often involves comedones, which may progress to inflammatory papules, pustules, nodules, and cysts in severe cases, potentially resulting in permanent scarring [1,2]. As the most common subtype, acne vulgaris primarily occurs during adolescence and may persist into adulthood, pathologically characterized by chronic inflammation of pilosebaceous units. Although non-life-threatening, its psychosocial impact warrants serious clinical attention [3]. Substantial evidence indicates that acne vulgaris and post-inflammatory hyperpigmentation significantly impair quality-of-life metrics in adolescents, adversely affecting self-image perception, social interaction competence, and mental health - particularly hindering the development of self-esteem and identity formation. Consequently, early clinical intervention and standardized therapeutic protocols are of paramount importance [4]. Contemporary medical management primarily employs topical agents, with retinoids and antimicrobials demonstrating established efficacy in clinical practice [5]. However, monotherapy approaches present notable limitations, including high adverse effect incidence, diminishing therapeutic returns, and antibiotic resistance development. In contrast, integrated Traditional Chinese and Western Medicine (TCM-WM) approaches demonstrate superior therapeutic advantages. This study implemented a combined regimen of oral TCM decoction with topical clindamycin phosphate gel to evaluate the clinical efficacy of TCM-WM integration for acne vulgaris. The detailed research outcomes are presented as follows.

2. Information

2.1 General Information

A total of 70 acne vulgaris patients treated at our dermatology department between June 2023 and June 2024 were enrolled in this randomized, single-blind, parallel-controlled study. Using a computer-generated randomization sequence based on random number tables, participants were allocated to either the control group (n=35) or observation group (n=35). The control group comprised 18 males and 17 females, aged 15-35 years (mean 23.17±6.09), with disease duration ranging from 7-180 days (mean 35.92±31.71 days). The observation group included 20 males and 15 females, aged 15-35 years (mean 23.83±5.91), showing similar disease duration (7-180 days, mean 34.62±30.17 days). No statistically significant differences were observed between groups regarding baseline characteristics including age, gender, and disease duration (all $P>0.05$), confirming comparability (Table 1).

2.2 Diagnostic Criteria

Western Medical Diagnostic Criteria [6]: The condition predominantly affects sebum-rich areas, including the face (cheeks, forehead, and chin), chest, and back. Characteristic clinical manifestations consist of various types of comedones, categorized as open (blackheads, presenting as dilated follicular orifices with oxidized keratin plugs) and closed (whiteheads, appearing as skin-colored micropapules with closed follicular openings). In severe cases, lesions may progress to erythematous inflammatory papules (localized erythematous elevations), pustules (raised lesions with purulent accumulation), nodules (firm, deep inflammatory infiltrates), or cysts (large, fluctuant inflammatory sac-like structures).

Traditional Chinese Medicine (TCM) Syndrome Differentiation Criteria [7]: Lung Channel Wind-Heat Syndrome: Lesions primarily manifest as inflammatory papules (red or skin-colored) and comedones, potentially accompanied by pruritus or pain; dry mouth and throat, scanty dark urine, and dry stools; red tongue with thin yellow coating, floating rapid pulse. Gastrointestinal Dampness-Heat

Syndrome: Dominant lesions include erythematous papules and pustules with marked tenderness, accompanied by excessive sebum production on the face and trunk; bitter taste and halitosis, poor appetite, loose or sticky stools (alternatively constipation), and dark urine; red tongue with yellow greasy coating, slippery rapid or wiry rapid pulse. Phlegm-Stasis Congealing Syndrome: Lesions predominantly present as dark-red nodules and cysts, potentially complicated by pustules, with protracted disease course; anorexia and loose stools; dark purple tongue or ecchymosis, deep thin or choppy pulse.

2.3 Eligibility Criteria

Inclusion Criteria: (1) Clinically confirmed diagnosis of acne vulgaris; (2) No systemic or topical anti-acne treatments administered within 3 months prior to enrollment; (3) Signed informed consent with commitment to complete the treatment protocol and follow-up schedule.

Exclusion Criteria: (1) Known hypersensitivity to the Chinese herbal preparations used in the study; (2) Women planning pregnancy, currently pregnant, or lactating; (3) Concurrent facial dermatoses (e.g., rosacea, seborrheic dermatitis); (4) Severe psychiatric disorders compromising treatment compliance; (5) Inability to guarantee scheduled follow-up visits or complete the study protocol.

3. Methodologies

3.1 Treatment

Patients in the control group cleansed affected areas with warm water twice daily followed by topical application of clindamycin phosphate gel (2-3 applications/day). The standardized administration procedure required: (1) ensuring complete skin dryness, (2) applying an appropriate quantity (approximately 0.5g per 100cm² lesion area) with uniform distribution using sterile gloved fingertips, (3) gentle circular massage until full absorption (≈30 seconds per application). The observation group received additional oral administration of TCM decoction containing: Flos Lonicerae Japonicae (30g), Radix Scutellariae Baicalensis (15g), Fructus Forsythiae Suspensae (15g), Folium Eriobotryae Japonicae (12g), Herba Hedyotis Diffusae (15g), Flos Chrysanthemi Indici (20g), Radix Isatidis Seu Baphicacanthis (15g), Radix Salviae Miltiorrhizae (12g), Herba Taraxaci Mongolici (20g), Radix Paeoniae Rubra (15g), Radix Angelicae Dahuricae (10g), Rhizoma Coptidis (8g), Radix et Rhizoma Rhei (8g, added during final 5 minutes of decoction), Semen Coicis Lachryma-jobi (30g), and Radix Glycyrrhizae Uralensis (9g). The decoction protocol specified: (1) cold water immersion (3cm above herb level) for 10 minutes, (2) initial vigorous boiling followed by 20-30 minute simmering, (3) double extraction with final 5-minute addition of late-entry herbs, (4) combination of filtrates for twice-daily oral administration (150mL/dose) 1-hour postprandial. Both groups received identical lifestyle instructions: alcohol/spicy food abstinence, UV avoidance, and cosmetic discontinuation. Treatment cycles spanned 7 days with efficacy and adverse event assessments at days 14 and 28.

3.2 Observation Indicators

3.2.1 Clinical indicators

Clinical symptoms and signs were evaluated at baseline, day 14, and day 28 of treatment, with quantitative measurements of lesional area changes and systematic counts of comedones (open and closed), inflammatory papules, pustules, nodules, and cysts. Adverse events including systemic manifestations (e.g., dizziness, nausea) and local reactions (e.g., erythema, stinging pain) were monitored throughout the study period. A comprehensive skin lesion assessment was performed at baseline, interim evaluation conducted at day 14, and final efficacy determination completed at day 28, with all measurements performed by blinded evaluators using standardized photographic documentation and lesion mapping techniques under consistent lighting conditions (5000K color temperature, 1000 lux intensity).

3.2.2 Assessment of efficacy

Therapeutic outcomes were classified into four grades according to established clinical guidelines [8]: (1) Clinical cure: Complete resolution of lesions with disappearance of all symptoms/signs (efficacy index ≥90%); (2) Markedly effective: Significant clinical improvement with ≥60% lesion clearance (60%≤efficacy index<90%); (3) Effective: Partial symptom relief with ≥20% lesion reduction (20%≤efficacy index<60%); (4) Ineffective: No improvement or worsening of symptoms (efficacy index<20%). The total effective rate was calculated as: (number of cured + markedly effective + effective cases) / total cases × 100%, with efficacy index determined by the formula: [(pre-treatment score - post-treatment score) / pre-treatment score] × 100%, where lesion severity was scored using the 5-point Global Acne Grading System (0=no lesions, 4=severe involvement) for standardized evaluation.

3.3 Statistical Analyses

Data analysis was performed using SPSS 26.0 (IBM Corp.). Continuous variables were expressed as mean ± standard deviation ($\bar{x}\pm s$), while categorical data were presented as frequencies and percentages. Normality distribution was assessed by Shapiro-Wilk test and homogeneity of variance by Levene's test. Parametric data (normally distributed with equal variance) were analyzed using independent samples t-test, whereas non-parametric data utilized Mann-Whitney U test. Categorical variables were evaluated by Pearson's chi-square test when expected frequencies ≥5, continuity-corrected chi-square when $1 \leq$ expected frequencies < 5, and Fisher's exact test for expected frequencies <1. The statistical significance threshold was set at $\alpha=0.05$ (two-tailed), with $P < 0.05$ considered statistically significant. All statistical procedures conformed to the International Statistical Institute's guidelines for biomedical research reporting.

4. Results

Table 1: Comparison of general information of two groups (cases).

Groups	Number	Sexes		Age (x± s, y)	Disease duration (x± s, d)	χ2	P
		Male	Women				
Observation group	35	20	15	23.83±5.91	38.23±41.31		
Control subjects	35	18	17	23.17±6.09	36.71±40.78	3.883	0.561

Table 2: Comparison of the efficacy of the two groups for 14 days of treatment (cases)

Groups	Number	Healing	Tangible effect	Improvement	Null	Effective rate	χ2	P
Observation group	35	1	13	16	5	85.71		
Control subjects	35	0	8	19	8	77.14	3.140	0.317

Table 3: Comparison of the efficacy of the two groups for 28 days of treatment (cases)

Groups	Number	Healing	Tangible effect	Improvement	Null	Effective rate	χ2	P
Observation group	35	19	11	4	1	97.14	10.281	0.016
Control subjects	35	8	11	12	4	88.57		

4.1 Comparison of Clinical Efficacy between the Two Groups

After 14 days of treatment, the effective rate in the observation group was higher than that in the control group, but there was no significant difference in the overall cure rate and effective rate between the two groups ($P > 0.05$).After 28 days of treatment, the effective rate in the observation group was significantly higher than that in the control group, with a statistically significant difference ($P < 0.05$), indicating that the overall cure rate and effective rate of the observation group were markedly superior to those of the control group. See Tables 2 and 3.

4.2 Adverse Reaction Observation

During the treatment, only one patient experienced mild local redness and a stinging sensation, which did not affect subsequent administration. No systemic or local adverse reactions were observed in the remaining patients.

5. Talk Over

Acne vulgaris, a common chronic inflammatory disease of the pilosebaceous unit among adolescents, has a pathophysiological process that is not yet fully understood. Current studies have confirmed that key factors such as endocrine dysregulation leading to hyperactive sebaceous gland secretion, abnormal keratinization of the pilosebaceous duct, and microbial dysbiosis — particularly the overproliferation of *Cutibacterium acnes* (formerly *Propionibacterium acnes*) — are associated with the pathogenesis of the disease. The main contributing factors include endocrine influences, excessive sebum production, abnormal follicular keratinization, and microbial imbalance. Furthermore, recent research has revealed that the activation of inflammatory cascades, immune dysregulation, genetic predisposition, and psychosocial factors also play roles in the development of acne [9]. Acne vulgaris is easily diagnosed based on its typical clinical manifestations but must be differentiated from rosacea, occupational acne, lupus miliaris disseminatus faciei, and acneiform drug eruptions induced by bromine or iodine. Rosacea primarily affects middle-aged adults (30–50 years old), with persistent erythema and telangiectasia predominantly involving the nose and surrounding areas; it lacks comedones and is typically confined to the central facial region. Occupational acne is often triggered by prolonged exposure to industrial compounds such as petroleum derivatives and is clinically characterized by multiple keratotic follicular papules on exposed areas (e.g., face, forearms), with epidemiological features showing occupational clustering. Lupus miliaris disseminatus faciei predominantly occurs in adults, presenting as symmetrically distributed, smooth-surfaced, purplish-red nodules on the cheeks, demonstrating a characteristic "apple-jelly" appearance under diascopy. Bromine- or iodine-induced acneiform eruptions have a clear history of bromide/iodide use, exhibit generalized rash distribution without typical comedones, and lack a specific age predilection.

Clindamycin phosphate gel, a commonly used topical medication for acne vulgaris, has been demonstrated in existing clinical studies to exhibit a dual mechanism of action in acne treatment, combining significant antibacterial activity — particularly against pathogenic microorganisms such as Cutibacterium acnes—with distinct anti-inflammatory effects that effectively reduce perifollicular inflammatory responses. It can markedly alleviate the clinical symptoms of inflammatory lesions and help prevent the formation of new acne lesions, with a low incidence of adverse reactions and good patient tolerance [10]. However, monotherapy with this agent shows limited efficacy in reducing disease recurrence rates and often fails to achieve the therapeutic goal of complete clinical remission. Additionally, it provides suboptimal clinical efficacy for non-inflammatory lesions such as comedones.

Traditional Chinese Medicine (TCM) has a long-standing understanding of acne vulgaris, historically classified in medical texts under terms such as "lung-wind pimples" or "alcohol-induced pimples". The earliest discussion of its etiology and pathogenesis dates back to the *Yellow Emperor's Inner Canon* (*Huangdi Neijing*), where the *Basic Questions·Chapter on Vital Qi Connecting with Heaven* first described its mechanism, stating, "Cold constrained [in the skin] forms red papules, and stagnation develops into acne," elucidating the pathological process of skin lesions caused by exposure to pathogenic factors after sweating. By the Ming and Qing dynasties, medical scholars had developed a deeper understanding. Qi Kun, in *Great Compendium of Surgery* (*Waike Dacheng*), attributed "lung-wind alcohol pimples" to blood-heat stagnation in the Lung Meridian. Chen Shigong, in *Orthodox Manual of Surgery* (*Waike Zhengzong*), innovatively proposed that dampness-heat of the spleen-stomach and stagnant heat in the Lung Meridian jointly contribute to the disease, positing that excessive consumption of greasy foods leads to intense stomach fire,

which ascends to affect the lungs, resulting in facial sores. These historical perspectives reveal that TCM etiology of acne primarily involves interactions between exogenous "six excesses" (wind, cold, dampness) and internal factors (blood-heat, spleen-stomach dampness-heat, deficiency). Modern research interprets its essence as the occlusion of hair follicles due to both external pathogens constraining the surface and internal heat accumulation, with lung-stomach stagnant heat and dampness-heat interaction constituting the core pathological links—a theoretical framework critical for clinical pattern differentiation and treatment. Contemporary scholars have further refined acne's pathogenesis. Professor Zhu Renkang, based on qi-blood theory, emphasized the interdependence between skin interstices' function and qi-blood circulation, establishing three primary patterns in clinical practice: dual blazing of qi and blood, qi stagnation with blood stasis, and qi deficiency with floating heat. His individualized therapeutic approach addressing both root and manifestation has demonstrated favorable clinical outcomes [11]. Professor Sun Zhanxue, building on the classical "stagnation-induced acne" theory, detailed the dynamic process of "stagnant heat" pathogenesis: early-stage visceral dysfunction causing sebum accumulation (non-inflammatory lesions); progressive phase with heat-toxin transformation manifesting as erythematous pustules; and chronic phase where heat-toxin damages collaterals, leading to hyperpigmentation and scarring [12]. Professor Wang Ke, from the Tian Gui-Chong Ren theoretical system, proposed a dual-pathogenesis model: congenital endocrine dysregulation as the foundational cause, and acquired dietary/lifestyle-induced spleen-stomach dysfunction as a key aggravating factor, with subsequent qi-blood stasis and phlegm-dampness coagulation during disease progression [13]. These theoretical innovations have significantly enriched TCM's understanding of acne.

Based on an in-depth analysis of the clinical manifestations and pathological characteristics of acne vulgaris, the author posits that the syndrome differentiation and treatment of this disease should emphasize pathogenic factors such as wind pathogen, damp turbidity, heat toxin, phlegm coagulation, and blood stasis. Of particular note is the clinical presentation in female patients caused by endocrine fluctuations, which in TCM theory is primarily attributed to Chong Ren disharmony. Targeting the fundamental pathogenesis of the disease, the therapeutic principle focuses chiefly on clearing heat and resolving dampness, supplemented by additional methods such as dissolving phlegm and softening hardness, or activating blood circulation and freeing the collaterals according to specific syndrome patterns. The proposed treatment strategy advocates for an integrated intervention approach combining oral medication with external therapy.

The principal herbs in the formula are Lonicerae Japonicae Flos (Jinyinhua) and Scutellariae Radix (Huangqin). According to *Shennong Bencao Jing* (Divine Farmer's Materia Medica), Lonicerae Japonicae Flos is cold in nature and sweet in taste, with effects of clearing heat-toxin, cooling blood, and dissipating stasis, making it suitable for external contraction of wind-heat and skin sores. Scutellariae Radix, with its bitter-cold nature, has the function of clearing heat and drying dampness. *Bencao Jingshu* (Annotations on the Materia Medica) explains that its "purifying and descending property can expel pathogens, the bitter flavor can dry dampness, and the cold nature can counteract heat." The two herbs work synergistically to exert heat-clearing and fire-draining effects. The assistant herb group includes five medicinal substances such as Forsythiae Fructus (Lianqiao) and Eriobotryae Folium (Pipaye). Forsythiae Fructus has been praised by physicians throughout history as an essential herb for treating sores and ulcers, with effects of resolving toxicity and dissipating nodules. Eriobotryae Folium excels at clearing and draining lung-stomach stagnant heat. *Shiliao Bencao* (Dietary Therapy Materia Medica) records its ability to treat skin conditions such as "lung-wind sores." It is combined with Hedyotis Diffusae Herba (Baihuasheshecao) and Taraxaci Herba (Pugongying) to collectively enhance the heat-clearing and toxin-resolving effects. Addressing the disease mechanism of heat-toxin stagnation leading to qi-blood stasis and obstruction, the formula includes adjuvant herbs such as Salviae Miltiorrhizae Radix (Danshen) and Paeoniae Radix Rubra (Chishao) to activate blood circulation and resolve stasis. Among them, Angelicae Dahuricae Radix (Baizhi) has a pungent-dispersing property that can expel pathogens outward. Furthermore, Coptidis Rhizoma (Huanglian) and Rhei Radix et Rhizoma (Dahuang) are used to free the fu organs and drain heat, combined with Coicis Semen (Yiyiren) to disinhibit dampness and expel pus, embodying the therapeutic principle of "giving pathogens a pathway for discharge." The messenger herb Glycyrrhizae Radix et Rhizoma (Gancao) both assists in clearing heat and resolving toxicity and harmonizes the various herbs.For cases with nodules and cysts, add Thunbergii Fritillariae Bulbus (Zhebeimu) 12g and Curcumae Rhizoma (Ezhu) 12g; for severe dampness, add Artemisiae Scopariae Herba (Yinchenhao) 15g and Atractylodis Rhizoma (Cangzhu) 10g; for yin deficiency, add Rehmanniae Radix (Shengdi) 15g, Anemarrhenae Rhizoma (Zhimu) 10g, and Scrophulariae Radix (Xuanshen) 10g; for thoroughfare and conception vessel disharmony, add Bupleuri Radix (Chaihu) 15g, Cyperi Rhizoma (Xiangfu) 10g, and Leonuri Herba (Yimucao) 15g; for excessive stomach heat, add Eupatorii Herba (Peilan) 12g and Gypsum Fibrosum (Shigao) 15g.

Modern research indicates that Lonicerae Japonicae Flos (Jinyinhua) contains active components such as chlorogenic acid, which exhibit broad-spectrum antibacterial and anti-inflammatory effects [14]. Scutellariae Radix (Huangqin) contains baicalin and other constituents that significantly inhibit the growth of *Cutibacterium acnes* (formerly *Propionibacterium acnes*) [15], with the two herbs synergistically exerting heat-clearing and detoxifying effects. In the assistant herb combination, phenylethanoid glycosides from Forsythiae Fructus (Lianqiao) demonstrate notable anti-inflammatory activity [16], while ursolic acid from Eriobotryae Folium (Pipaye) cooperatively regulates sebum secretion [17]. Oleanolic acid from Hedyotis Diffusae Herba (Baihuasheshecao) and taraxasterol from Taraxaci Herba (Pugongying) collectively enhance antibacterial and anti-inflammatory efficacy [18,19]. Among the adjuvant and messenger herbs, tanshinone IIA from Salviae Miltiorrhizae Radix (Danshen) reduces sebum production by modulating androgen receptors [20]; paeoniflorin from Paeoniae Radix Rubra (Chishao) improves microcirculation [21]; coumarins from Angelicae Dahuricae Radix (Baizhi) promote inflammation resolution [22]; berberine from Coptidis

Rhizoma (Huanglian) and anthraquinones from Rhei Radix et Rhizoma (Dahuang) synergistically regulate gut microbiota [23,24]; while glyceryl trioleate from Coicis Semen (Yiyiren) suppresses inflammatory responses via the PPARγ pathway [25]. The entire formula achieves comprehensive therapeutic effects—anti-inflammatory, antibacterial, sebum-regulating, and follicular microenvironment - improving — through integrated multi-component, multi-pathway, and multi-target modulation, fully embodying the holistic regulatory characteristics of traditional Chinese medicine.

The results of this study indicate that no statistically significant difference in overall efficacy was observed between the two groups of patients during the initial treatment phase (14 days), which may be attributed to the insufficient observation period and limited sample size. However, upon extending the treatment to 28 days, the combined therapy group demonstrated significantly higher clinical cure rates and total effective rates compared to the single Western medicine treatment group. Safety assessments revealed that no serious adverse events occurred in any participants during the intervention period. These findings suggest that the integrated traditional Chinese and Western medicine approach for treating acne vulgaris not only significantly enhances clinical outcomes but also exhibits favorable treatment safety, with its comprehensive efficacy markedly superior to that of topical antimicrobial monotherapy, highlighting its substantial clinical application value.

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