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Clinical Study

Treatment of acne vulgaris with auricular acupoint pricking-bloodletting plus auricular point sticking therapy: a randomized controlled study

耳穴刺络放血加耳穴贴压法治疗寻常性痤疮：随机对照研究

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Abstract

Objective: To observe the clinical efficacy of auricular point pricking-bloodletting plus auricular point sticking therapy for acne vulgaris.

Methods: A total of 66 patients with acne vulgaris were randomized into an observation group and a control group by the random number table, with 33 cases in each group. The observation group was treated with auricular point pricking-bloodletting plus auricular point sticking therapy, and the control group was treated only with auricular point sticking therapy. The treatments of both groups were performed twice a week, 4 weeks as a course of treatment, for 3 courses in total. The scores of skin lesions and dermatology life quality index (DLQI) scores were recorded before and after treatment to assess the clinical efficacy.

Results: During the trial, there were 3 cases of drop-out both in the observation group and the control group. After 3 courses of treatment, the total effective rate of the observation group was 96.7%, while that of the control group was 76.7%. The difference between the two groups was statistically significant (P<0.05). The intra-group comparison showed that the scores of skin lesion and DLQI were both decreased with the increase of treatment times, that was, the scores were lower than those at the previous time point (all P<0.05). After 1, 2, and 3 courses of treatment, the scores of skin lesion and DLQI of both groups were statistically different from those of the same group before treatment (all P<0.05). At every time point during the treatment, the scores of skin lesion and DLQI of the observation group were lower than those of the control group, and the differences between the two groups were statistically significant (all P<0.05).

Conclusion: Auricular point pricking-bloodletting plus auricular point sticking has a better curative effect than auricular point sticking therapy alone in the treatment of acne vulgaris, and has a time-effect correlation.

Keywords: Acupoint Therapy; Auricular Point Sticking; Bloodletting Therapy; Otopoint, Cheek (LO_5); Point, Erjian (EX-HN 6); Otopoint, Lung (CO_{14}); Otopoint, Shenmen (TF_4); Acne

【摘要】目的：观察耳穴刺络放血加耳穴贴压治疗寻常性痤疮的临床疗效。**方法：**将66例寻常性痤疮患者根据随机数字表分为观察组和对照组，每组33例。观察组采用耳穴刺络放血加耳穴贴压治疗，对照组仅采用耳穴贴压治疗。两组均每周治疗2次，4周为1个疗程，共治疗3个疗程。分别于治疗前和治疗后记录患者皮损积分和皮肤病生活质量指数(DLQI)积分，并据此进行疗效评定。**结果：**试验过程中观察组和对照组均脱落3例。3个疗程结束后，观察组总有效率为96.7%；对照组总有效率为76.7%，差异有统计学意义(P＜0.05)。组内比较显示，两组患者皮损积分和DLQI积分均随治疗次数的增加而降低，后一时间点积分均低于前一时间点(均P＜0.05)。两组患者治疗1、2、3个疗程后的皮损积分和DLQI积分均与本组治疗前比较有统计学差异(均P＜0.05)。组间比较显示，治疗后每个时间点，观察组皮损积分与DLQI积分均低于对照组，组间差异均有统计学意义(均P＜0.05)。**结论：**耳穴刺络放血加耳穴贴压治疗寻常性痤疮的临床疗效优于单独耳穴贴压治疗，且存在时间-效应关系。

【关键词】穴位疗法；耳穴贴压；放血疗法；耳穴，面颊；穴，耳尖；耳穴，肺；耳穴，神门；痤疮

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Acne can be classified into four types: acne, acne subtypes, time-related acne, and acne-like rashes. Of which, the acne can be divided into acne vulgaris, acne conglobata, pyogenic acne, the follicular occlusion triad, perioral dermatitis and pyoderma faciale. Acne vulgaris is the most common type, a chronic folliculosebaceous inflammatory disease, often accompanied by seborrhea[1]. The pathogenesis of acne is complicated. At present, Western medicine mainly studies and treats the disease from aspects of follicular keratosis, acne propionibacterium effects, increased sebum secretion and inflammation[2].

In recent years, there are more reports of auricular therapy for acne vulgaris, such as auricular point needle-embedding[3], auricular point bloodletting[4] and auricular point sticking[5], but lacks of rigorously designed randomized controlled trials.

We have found that auricular point pricking-bloodletting plus auricular point sticking can relieve the skin lesions and improve the quality of life for patients with acne vulgaris through our clinical practice[6]. The aim of this study was to observe the clinical efficacy of auricular point pricking-bloodletting plus auricular point sticking therapy for acne vulgaris and its time-effect correlation by randomized controlled trials, in order to provide evidence-based medical evidence for the treatment of acne vulgaris.

1 Clinical Materials

1.1 Diagnostic criteria

1.1.1 Diagnostic criteria of Western medicine

The diagnostic criteria of acne vulgaris referred to the *Guideline for Diagnosis and Treatment of Acne* (the 2014 revised edition)[7]: the lesions are mainly on the face, manifested as red inflammatory papules, pustules, blackheads or whiteheads comedo. Pillsbury grades as level I-IV (grade I: mainly acnes, with a small amount of papules and pustules, and the number of lesions <30; grade II: inflammatory papules, the number of lesions is 31-50; grade III: a large number of inflammatory papules, pustules, the number of lesions is 50-100, and nodules <3; grade IV: nodules, cystic acne or acne conglobata, total lesions >100, and nodules >3).

1.1.2 Criteria for syndrome differentiation of traditional Chinese medicine (TCM)

Syndrome differentiation classification referred to the *Criteria of Diagnosis and Therapeutic Effects of Diseases and Syndromes in Traditional Chinese Medicine*[8].

Syndrome of wind-heat in the lung meridian: acne, accompanied by thirst with desire for drink, constipation, short voidings of dark urine, a reddened tongue with thin yellowish coating, and string-like slippery pulse.

Syndrome of stomach-intestinal dampness-heat: acne, accompanied by halitosis, constipation, yellow urine, a reddened tongue with yellow slimy coating, and rapid slippery pulse.

Syndrome of stagnation of phlegm-dampness: dark red skin rash, visible sinus, difficulty healing for a long time, anorexia, abdominal distention, a dark reddened tongue with slippery slimy coating, and string-like slippery pulse.

Syndrome of yin deficiency with internal heat: acne, accompanied by tidal fever, night sweats, a reddened tongue lacking moisture and rapid fine pulse.

1.2 Inclusion criteria

Those who met the above diagnostic criteria for Western medicine and syndrome differentiation of TCM; aged 16-30 years; no medication related to acne treatment 1 month before this trial; no antibiotics, hormones or retinoids acid within 2 weeks before this trial; no externally used medicines for acne within 1 week before this trial; agreed to participate in this clinical trial and signed informed consent.

1.3 Exclusion criteria

Pregnant or parturient or breast-feeding women; occupational acne caused by chemical substances or acne caused by drugs; those with serious diseases of cardiovascular, cerebrovascular, liver, kidney, hematopoietic or endocrine systems; psychiatric patients; those who might get strong sun or ultraviolet rays during treatment; those with allergic constitution, sensitive skin or physical weakness; with acnes not on the face (such as neck, chest, or back acnes); those who participated in other clinical trials.

1.4 Elimination criteria

Those who were found out not meeting the inclusion criteria or meeting the exclusion criteria in the trial; those had other medication or therapy during the treatment that might influence the efficacy evaluation; with poor compliance that affected efficacy.

1.5 Shedding criteria

Those dropped out during the trial or with poor compliance; dropped out because of various reasons (including adverse reactions); unable to assess the efficacy due to irregular treatment, or incomplete data that affected efficacy and safety evaluation.

1.6 Suspension criteria

Those who presented with adverse reaction due to allergy or inadaptation to the intervention during the trial; there occurred major errors in the test protocol during the trial or major deviations in the implementation, which caused difficulty evaluating the effect; suspension due to participant's requirement or other reasons.

1.7 Statistical methods

All data were statistically analyzed by the SPSS version 20.0 statistical software. Measurement data were expressed as mean ± standard deviation ($\bar{x} \pm s$).

Independent sample *t*-test and Chi-square test were applied to the baseline comparison between groups. Mauchly's Test of Sphericity was applied to the outcomes of scores of skin lesion and dermatology life quality index (DLQI), to test whether the data met the repeated measurement model. Scores of skin lesion and DLQI score were analyzed by repetitive measurement and analysis of variance (general linear model). $P<0.05$ was considered to indicate a statistically significant difference.

1.8 General data

A total of 66 patients with acne vulgaris were enrolled from the Dermatology Department of Guo Yi Tang, the Clinic of Hebei University of Chinese Medicine between September 2015 and May 2016. All patients were randomly divided into an observation group and a control group by the random number table, with 33 cases in each group. The patients in the observation group were aged 20-24 years, with the shortest duration of 5 months and the longest of 4 years. And the patients in the control group were aged 19-26 years, with the shortest duration of 6 months and the longest of 3.5 years.

During the trial, 3 subjects dropped out in each group. All dropouts were unable to continue the treatment because of busy work or study. In the end, 30 patients in each group completed the treatment. There were no statistical differences in gender, age, duration of disease and the acne grading (all $P>0.05$), indicating that the two groups were comparable (Table 1).

Table 1. Comparison of baseline data between the two groups

Group	*n*	Gender (case)		Average age ($\bar{x}\pm s$, year)	Average duration ($\bar{x}\pm s$, month)	Pillsbury grading			
		Male	Female			I	II	III	IV
Observation	30	6	24	20.9±1.0	28.0±10.1	5	17	5	3
Control	30	7	23	20.8±1.3	27.8±10.8	7	17	5	1
Statistics		0.10[1)]		0.22[2)]	0.05[2)]			1.33[1)]	
P value		0.75		0.82	0.96			0.72	

Note: 1) x^2 value; 2) *t*-value

2 Research Methods

2.1 Randomized grouping

The SAS statistical software was used to generate a 1:1 random number grouping table. The patients were divided into an observation group and a control group by this random number table, with 33 cases in each group. The randomization was managed by a specialist who did not participate in the trial. The physician was informed of the treatment protocol by telephone for 5-10 min before treatment.

2.2 Blind implementation

All participants were unaware of the grouping for the treatment received. In the process of the trial, the physician, the recorder and the statistician were separated. No one but the physician was aware of the grouping.

2.3 Equipment for intervention

Disposable venous blood sampling needle, with specification of 0.7 mm in diameter and 25 mm in length [State Food and Drug Administration (Zhun) No. 3411584, 2014]; *Wang Bu Liu Xing* (*Semen Vaccariae*) (60 grains/bag).

2.4 Auricular point location

The auricular point location referred to the *Nomenclature and Location of Auricular Points* (GB/T 13734-2008)[9].

2.5 Grouping and interventions

2.5.1 Observation group

Auricular point pricking-bloodletting: The physician first observed whether the patient's external ear was red and swelling or had any infection. After gently rubbing the patient's auricle till congested and hot, the physician routinely disinfected the skin of external ear with 0.2% iodophor. Then the physician used disposable venous blood sampling needle to prick Erjian (EX-HN 6), the dorsal collateral vein of the ear and at the earlobe (the cheek area), and extruded 3-5 mL blood in total[10].

Auricular point sticking: Main points were Lung (CO_{14}), Shenmen (TF_4), Endocrine (CO_{18}) and Adrenal Gland (TG_{2p}). Large Intestine (CO_7) was added for syndrome of wind-heat in the Lung Meridian; Spleen (CO_{13}), Stomach (CO_4) and Large Intestine (CO_7) were added for syndrome of dampness-heat in the stomach and intestine; Heart (CO_{15}) and Sympathetic (AH_{6a}) were added for syndrome of stasis and stagnation due to phlegm-dampness; Sympathetic (AH_{6a}) and Kidney (CO_{10}) were added for syndrome of internal heat due to yin deficiency[11].

The above treatments were performed twice a week, 4 weeks as a course of treatment, for 3 courses in total.

2.5.2 Control group

The control group received the same auricular point sticking therapy as the observation group. The acupoints, interventions and treatment courses were the same as those in the observation group.

2.6 Cautions

Cleaned the skin with warm water during the treatment, and prohibited chemical products such as facial cleanser, cosmetics or other drugs; prohibited hand squeezing, rubbing, and touching skin lesions; ate less spicy, cold or greasy food.

3 Observation of Curative Efficacy

3.1 Observation items

3.1.1 The score of skin lesion

According to the *Guiding Principles for Clinical Study of New Chinese Medicines*[12], the scoring items and criteria were developed, including the type, area, number, color, size, hardness and tenderness and itching of the skin lesion. The full score was 83 points, and the higher the score, the more obvious the symptoms. The condition of skin lesion was assessed and recorded before the treatment and at the end of every treatment course.

3.1.2 DLQI[13]

The Chinese version of DLQI was applied in this study to assess patients' quality of life (QOL). There were 10 items in this scale, using 0 to 3 points scoring method. 0 point stood for completely none, 1 point for less, 2 points for much，and 3 points for very much. The highest score was 30 points. The higher the score, the worse the QOL. DLQI was assessed and recorded before the treatment and after the end of every treatment course.

3.2 Criteria of curative efficacy

According to the *Criteria of Diagnosis and Therapeutic Effects of Diseases and Syndromes in Traditional Chinese Medicine*[8], the efficacy criteria were established.

Cured: The number of skin lesion was 0, or the reduction of the score of skin lesion ≥90%, no occurrence of new lesion, and subjective symptoms disappeared.

Marked effect: The reduction of the score of skin lesion ≥70%, but <90 %.

Effective: The reduction of scores of skin lesion ≥30%, but <70 %.

Invalid: There was no obvious change in skin lesion and symptoms, or the reduction of the score of skin lesion <30 %.

3.3 Results

3.3.1 Comparison of efficacy between the two groups

The total effective rate was 96.7% in the observation group and 76.7% in the control group. By Chi-square test, the comparison results were presented as x^2=15.486, P=0.001, suggesting that the total effective rate difference between the two groups was statistically significant, and the observation group was superior to the control group (Table 2).

3.3.2 Comparison of the score of skin lesion between the two groups

The score of skin lesion in the two groups had time-effect correlation, that was, the scores decreased with the increase of treatment times, and the scores were lower than those at the previous time point (all P<0.05). After 1, 2, and 3 courses of treatment, the scores of skin lesion were statistically different from those of the same group before treatment (all P<0.05). The scores of skin lesion had the group effect, which was, the scores at three time points during treatment in the observation group were all lower than those in the control group, and the differences between the two groups were statistically significant (all P<0.05). There were interaction effect between time and group, presented as F=22.213, P=0.00, that was, the differences between the two groups were significant with the trends of time change (Table 3).

Table 2. Comparison of clinical efficacy between the two groups after treatment (case)

Group	n	Cured	Marked effect	Effective	Invalid	Total effective rate (%)
Observation	30	2	10	17	1	96.7[1)]
Control	30	0	0	23	7	76.7

Note: Compared with the control group, 1) P<0.05

Table 3. Comparison of the score of skin lesion between the two groups before and after treatment ($\bar{x}$ ±s, point)

Group	n	Before treatment	After 1 treatment course	After 2 courses of treatment	After 3 courses of treatment
Observation	30	34.0±15.05	22.6±11.04[1)4)]	16.5±7.60[1)2)4)]	10.5±5.30[1)2)3)4)]
Control	30	33.1±14.83	28.5±12.01[1)]	24.2±10.11[1)2)]	20.0±9.10[1)2)3)]

Note: Compared with the same group before treatment, 1) P<0.05; compared with the same group after 1 treatment course, 2) P<0.05; compared with the same group after 2 courses of treatment, 3) P<0.05; compared with the control group at the same time point, 4) P<0.05

3.3.3 Comparison of DLQI score between the two groups

The DLQI scores in the two groups had the time-effect correlation, that was, the scores decreased with the increase of treatment times, and the scores were lower than those at the previous time point (all $P<0.05$). After 1, 2, and 3 courses of treatment, the DLQI scores were statistically different from those of the same group before treatment (both $P<0.05$). The DLQI scores had the group effect, which was, the scores at three time points in the observation group were all lower than those in the control group, and the differences between the two groups were statistically significant (both $P<0.05$). There were interaction effect between time and group, presented as $F=5.642$, $P=0.001$, that was, the differences between the two groups were significant with the trends of time change (Table 4).

Table 4. Comparison of DLQI score between the two groups before and after treatment ($\bar{x}\pm s$, point)

Group	*n*	Before treatment	After 1 treatment course	After 2 courses of treatment	After 3 courses of treatment
Observation	30	20.33±0.64	15.77±0.52[1)4)]	12.7±0.49[1)2)4)]	8.87±0.37[1)2)3)4)]
Control	30	20.73±0.64	17.13±0.51[1)]	14.2±0.48[1)2)]	11.03±0.44[1)2)3)]

Note: Compared with the same group before treatment, 1) $P<0.05$; compared with the same group after 1 treatment course, 2) $P<0.05$; compared with the same group after 2 courses of treatment, 3) $P<0.05$; compared with the control group at the same time, 4) $P<0.05$

4 Discussion

At present, commonly used auricular acupoint therapy includes acupuncture, bloodletting, sticking, and needle-embedding. The effects of different stimulations generate at different times. Immediate effect means that a disease or some disease symptom and index has an obvious reduction or improvement or recovery in a short period of time through one-time treatment or after the first treatment. The accumulation effect, relative to the immediate effect, refers to the long-term effects of treatment over time. It has been found that the auricular acupoint therapy has outstanding immediate and accumulation effects in analgesia, antihypertension, and glucose-lowering[14-15].

Our previous study confirmed that auricular acupoint pricking-bloodletting plus auricular point sticking could relieve the pain, redness and itching of facial acne immediately. Meanwhile, in this study, it was found that the scores of skin lesions and DLQI were both decreased with the increase of treatment times, and the scores at each time point during treatment in the observation group were all lower than those in the control group, and the differences between the two groups were statistically significant (both $P<0.05$). The result indicated that auricular acupoint pricking-bloodletting plus auricular point sticking therapy had certain efficacy for acne vulgaris with accumulation effect. This suggested that it was more appropriate for doctors to set a reasonable time interval and treatment course in clinic, in order to achieve the best efficacy. We would also do more in-depth work in this regard in the future.

The ear is the place where whole body meridians gather. Among them, the six yang meridians all enter in the ear or cross at anterior, posterior, superior of the ear, and thus are closely related to the ear. The six yin meridians are also related to the ear through divergent branches and divergent collaterals. The meridians and collaterals of the whole body are interiorly and exteriorly related, superiorly and inferiorly connected, forming infinite circulations. Therefore, by stimulating the auricular acupoints, the physician can regulate the qi and blood circulation of the whole body and treat acne. There is certain correlation between the ear and five Zang organs, so it is also possible to regulate Zang-fu organs by stimulating auricular acupoints and then treat acne.

The distribution of auricular acupoints on auricle is like an 'inverted embryo'[16-17]. In 1970, Professor Zhang Ying-qing founded the bio-holographic law, which provided a theoretical basis for the distribution law of auricular acupoints. He believed that auricular acupoints could reflect disease information, and its mechanism was 'holographic reflection mechanism'[18]. Similarly, by stimulating auricular acupoints, the corresponding body organs can be adjusted. It can be said that the auricular acupoints are the reaction points and control points of the whole body.

Pricking Erjian (EX-HN 6) can clear heat and remove toxins, and pricking-bloodletting at the collateral vein of the ear can regulate viscera and clear heat to dispel stasis. The earlobe is divided into 9 areas, of which the cheek area corresponds to the cheek of the human body, and by stimulating this area, the local meridian can be unblocked, and the qi and blood flow of the cheek can be promoted. Endocrine (CO_{18}) has the function of regulating the body's endocrine. The combination of all the acupoints made the effect of clearing heat and detoxification, activating blood and unblocking collaterals, which is conducive to the recovery of acne.

Chinese medicine believes that pain and itching of sore and ulcer are related to heart. The 'heart' means fire and heat. Although the disease occurs on the skin surface, the cause of it is the dysfunction of Zang-fu

organs. Any kind of sore and ulcer is due to the stasis and stagnation caused by disharmony of Zang-fu organs and blocking of meridians and collaterals. Acne is mainly caused by heat and stasis. And the cause of heat and stasis is various, such as external contraction due to weakness, so that wind-heat attacks the face; or too much fatty food causes the dampness-heat in stomach and intestine; or emotional dysfunction, liver depression and qi stagnation, and depressed qi transforming into fire. Finally, the pathogenic heat attacks the face, transforming into acne. The accumulation of dampness-heat, or the long-term qi stagnation, the unsmooth blood circulation, and the obstruction of meridians and collaterals, will also cause acne[19].

Collateral vessel pricking-bloodletting method is a traditional Chinese medicine external treatment that punctures a specific acupoint, lesion, surface venule or pathological reaction point by needles to release appropriate amount of blood. The internal pathogenic blood is the cause of diseases. Bloodletting is a way to eliminate the pathogenic factors, and when pathogenic factors are eliminated, health will certainly be restored[20]. Collateral vessel pricking-bloodletting can promote sweating to release the exterior pathogens, nourish and harmonize the blood, unblock the meridians and collaterals, and purge toxin to eliminate the pathogenic factors, thus producing the effect in treating acne[21].

Modern research suggests that the pathogenesis of acne is related to abnormal regulation of sebaceous glands, bacterial infection, microbial overgrowth, cytokines and immune responses. Collateral vessel pricking-bloodletting therapy can improve the microcirculation, enhance local blood supply, promote metabolism, increase the phagocytic function of the reticuloendothelial system, thereby achieving anti-inflammation effect and repairing damaged skin[22-24]. In addition, collateral vessel pricking-bloodletting can inhibit the expression of inflammatory factors and the inflammatory response, accelerate the metabolism of inflammatory products, and promote inflammation release[25]. Modern study has also confirmed that collateral vessel pricking-bloodletting can affect various hormones, immune factors and electrolytes to improve the body's immune function and stimulate the body's defensive function[26].

This study compared the therapeutic effects of auricular point pricking-bloodletting plus auricular point sticking therapy and single auricular point sticking therapy in treating acne vulgaris. It was found that auricular point pricking-bloodletting plus auricular point sticking therapy had a better curative effect than auricular point sticking therapy alone, and thus could be used as a common therapy for treating acne vulgaris. Due to time reason, only 3 courses of treatment were performed in this study. Some patients showed effective but were not cured, so that it needs further study to see whether the scores of skin lesion and DLQI would continue decreasing with the increase of treatment course, and whether the cured rate would be further improved. In addition, it also requires further studies to see if the cured rate would be improved with the increase of treatment frequency while the treatment course remains unchanged. Meanwhile, blood analysis in the process of bloodletting to reveal the mechanism of auricular point bloodletting therapy for acne would be another focus in the next study.

Conflict of Interest

The authors declared that there was no potential conflict of interest in this article.

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Statement of Informed Consent

Informed consent was obtained from the patients in this study.

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