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Observation on the Clinical Efficacy of Microneedle Radiofrequency Combined with Bear Bile Powder in the Treatment of 40 Cases of Moderate to Severe Acne

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Abstract: *Objective*: To observe the clinical efficacy of microneedle radiofrequency combined with bear bile powder in the treatment of 40 cases of moderate to severe acne. *Methods*: 80 patients with moderate to severe acne admitted from July 2020 to July 2023 were selected as the study subjects. They were divided into two groups using a random number table method. The control group (40 patients) received microneedle radiofrequency treatment alone, while the observation group (40 patients) received a combination of microneedle radiofrequency and bear bile powder treatment. The treatment effects, skin lesion conditions [Global Acne Grading System (GAGS)], and adverse reactions were compared between the two groups. *Results*: The total effective rate of the observation group was 100.00%, which was higher than 87.50% of the control group ($P < 0.05$). After 4, 8, and 12 weeks of treatment, the GAGS scores of the observation group were lower than those of the control group ($P < 0.05$). There was no difference in the incidence of adverse reactions between the two groups ($P > 0.05$). *Conclusion*: Microneedle radiofrequency combined with bear bile powder can effectively treat moderate to severe acne, improve skin lesion conditions, and ensure treatment safety.

Keywords: Moderate to severe acne; Microneedle radiofrequency; Bear bile powder

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1. Introduction

Acne vulgaris is a common skin disease and a chronic inflammatory disease of the pilosebaceous unit. Although it does not pose a threat to life safety, it can significantly affect facial aesthetics and induce psychological issues, such as long-term anxiety, feelings of inferiority, unease, and loss of self-confidence [1]. Currently, there are various treatment methods for acne, including oral or topical medications, laser therapy, and microneedle radiofrequency. For moderate to severe acne, monotherapy with oral or topical medications can achieve certain effects, but the recurrence rate is high, and the possibility of complete recovery is small. Microneedle radiofrequency is a medical aesthetic laser technology that directly targets multiple tissues, such as the

sebaceous glands, destroying sebum, killing and inhibiting pathogenic bacteria such as Propionibacterium acnes, reducing skin inflammation, and achieving effective treatment [2]. Nowadays, monotherapy with medications or microneedle radiofrequency is common, while the combination of microneedle radiofrequency and medications is rare, especially studies on the combination of microneedle radiofrequency and oral bear bile powder. Based on this, this study selected 80 patients with moderate to severe acne to explore the efficacy of microneedle radiofrequency combined with bear bile powder. The report is as follows.

2. Materials and methods

2.1. General Information

The study was approved by the medical ethics committee, and patients signed informed consent forms. The sample size of the observation group and the control group was calculated using the formula n1=n2=2[(uα+uβ)/(δ/σ)]2 +0.25uα2. Based on the literature review, the estimated sample size was obtained as n1=n2=35 cases. However, considering that patients may switch to other treatment options or withdraw from the study due to various reasons during the study period, the sample size was increased to 40 cases per group, with a total sample size of 80 cases. All 80 patients were diagnosed with moderate to severe acne and were admitted to the hospital for treatment from July 2020 to July 2023. They were randomly divided into two groups using a random number table method, with 40 patients in each group.

Control group: 10 males and 30 females, aged 18–43 years old, with an average age of 30.89 ± 3.76 years old. The duration of the disease ranged from 6–42 months, with an average of 24.36 ± 4.71 months. There were 28 cases of moderate severity and 12 cases of severe severity. The skin lesion area ranged from 62–108 cm^2, with an average of 85.34 ± 6.82 cm^2. Observation group: 7 males and 33 females, aged 18–42 years old, with an average age of 30.25 ± 3.51 years old. The duration of the disease ranged from 6–44 months, with an average of 25.67 ± 4.94 months. There were 24 cases of moderate severity and 16 cases of severe severity. The skin lesion area ranged from 61–111 cm^2, with an average of 86.81 ± 6.99 cm^2. There was no difference in gender, age, or other information between the groups ($P > 0.05$).

Inclusion criteria: (1) Meet the diagnostic criteria in the "Chinese Acne Treatment Guidelines (2019 Revision)" [3]; (2) Age ≥ 18 years old; (3) No acne treatment was performed in the past month before the study; (4) Have indications for micro-needle radio frequency and bear bile powder treatment; (5) Understand the research content, treatment time, and precautions.

Exclusion criteria: (1) Have other wounds or sensitive skin on the face; (2) Have mental illness; (3) Have metal foreign bodies in the treatment area; (4) Have a history of keloid scars or hypertrophic scars; (5) Have a history of pigment loss or post-inflammatory pigmentation; (6) Have simple acne; (7) Have a pacemaker implanted in the heart; (8) Use other treatment options without permission, or give up treatment halfway.

2.2. Methods

Control group: Micro-needle radio frequency treatment was used alone. The treatment process and precautions were introduced verbally beforehand, and photos were taken before the treatment. Patients were instructed to clean their faces, apply a uniform and appropriate amount of topical anesthetic cream, which was then wiped off with a wet tissue after 30 minutes, and the face was cleaned and disinfected again. An acne needle was used for local needle cleaning, and electrode patches were attached to the patient's back. Based on the depth of the

skin lesion, 2 mm/3.5mm single-needle tips were selected. The micro-needle was inserted vertically into the skin lesion until the limiter touched the skin, and radiofrequency treatment was applied. The pulse width was adjusted to 150-250 ms and the power to 4-6W based on the actual response of the treatment and pain areas. The insulated needle was removed, and the procedure was repeated on the next skin lesion. During micro-needle radiofrequency, the needle was inserted as vertically as possible, with an interval of 2–3 mm between insertion points on the skin lesion. After completing the micro-needle radiofrequency treatment, a medical repair mask was provided to fully soothe the facial skin. The treatment was administered once every 4 weeks for a total of 3 times.

Observation group: Combined treatment with bear bile powder was used. The hospital prepared the bear bile powder according to a self-developed formula. It was ground into fine powder and packaged, with 25g per bag. The patients were instructed to take 1 bag 3 times a day before meals, mixed with warm water, for a continuous treatment of 12 weeks.

2.3. Observation indicators

(1) Treatment effect [4]: The reduction rate of lesion area was calculated using the formula: (lesion area before treatment - lesion area after treatment) ÷ lesion area before treatment × 100%. Markedly effective: reduction rate of lesion area > 70%; Effective: reduction rate of lesion area 30%-70%; Ineffective: reduction rate of lesion area < 30%; Total effective rate = (markedly effective + effective) ÷ total number of cases × 100%.

(2) Skin lesion condition: The Global Acne Grading System (GAGS) was used to evaluate multiple acne-prone areas such as the forehead, left cheek, right cheek, chin, and nose [5]. The lesion score represented the specific score of the area with the most severe inflammatory reaction. No lesions: 0 points; Visible ≥1 comedones: 1 point; Visible ≥1 pustules: 2 points; Visible ≥1 papules: 3 points; Visible ≥1 nodules: 4 points. The total score of the lesion area was calculated as the factor score multiplied by the lesion score. The comprehensive score was obtained by summing the total scores of each lesion area. Acne grading was performed based on the comprehensive score: 1–18 points for mild, 19–30 points for moderate, 31-38 points for severe, and ≥39 points for very severe.

(3) Adverse reactions: Dryness, burning sensation, desquamation, and pain.

2.4. Statistical methods

Comparative analysis was performed using SPSS 26.0. Enumeration data were expressed as percentages (%) and analyzed using the x^2 test. Measurement data followed a normal distribution and were analyzed using the t-test (or F-test). A P-value < 0.05 was considered statistically significant.

3. Results

3.1. Comparison of therapeutic effects between the two groups

The total effective rate was calculated, with the observation group showing a higher rate of 100.00% compared to the control group's 87.50% ($P < 0.05$) (**Table 1**).

Table 1. Comparison of therapeutic effects between the two groups (n/%)

Group	Markedly effective (n)	Effective (n)	Ineffective (n)	Total effective rate (%)
Observation group (*n*=40)	29	11	0	100.00
Control group (*n*=40)	17	18	5	87.50
x^2 value	-	-	-	5.333
P-value	-	-	-	0.021

3.2. Comparison of skin lesions between the two groups

After 4, 8, and 12 weeks of treatment, the GAGS score was lower in the observation group compared to the control group ($P < 0.05$) (**Table 2**).

Table 2. Comparison of skin lesions between the two groups (Mean ± SD, score)

Group	Before treatment	After 4 weeks	After 8 weeks	After 12 weeks
Observation group (n=40)	35.87 ± 4.76	26.05 ± 3.45	19.56 ± 2.85	13.42 ± 2.55
Control group (n=40)	35.21 ± 4.51	30.17 ± 3.87	24.56 ± 3.06	17.08 ± 2.84
t-value	0.637	5.026	7.562	6.065
P-value	0.526	<0.001	<0.001	<0.001

3.3. Comparison of adverse reactions between the two groups

The incidence of adverse reactions was calculated, and there was no difference between the two groups ($P > 0.05$) (**Table 3**).

Table 3. Comparison of adverse reactions between the two groups (n/%)

Group	Dryness (n)	Burning (n)	Desquamation (n)	Pain (n)	Adverse reaction rate (%)
Observation group (*n*=40)	1	1	1	1	10.00
Control group (*n*=40)	1	1	1	0	7.50
x^2 value	-	-	-	-	0.157
P-value	-	-	-	-	0.692

4. Discussion

The onset of acne is associated with excessive sebum secretion, excessive androgen secretion, infection by pathogenic bacteria such as Propionibacterium acnes, and blockage of follicular sebaceous ducts [6]. After entering puberty, androgen secretion rapidly increases, and testosterone promotes the production and secretion of large amounts of sebum. If the follicular sebaceous ducts undergo abnormal keratinization, it can lead to blockage of local sebaceous ducts, affecting the normal excretion of sebum and ultimately resulting in acne. Patients with mild acne have minor symptoms and a limited number of skin lesions, and can achieve complete recovery after appropriate treatment. However, patients with moderate to severe acne often have more pronounced acne lesions that affect facial aesthetics and have higher treatment requirements, especially

female patients. Micro-needle radiofrequency has been applied in the treatment of various facial diseases in recent years, including moderate to severe acne, wrinkles, acne scars, and atrophic scars. Generally, no special treatment is required for the use of micro-needle radiofrequency in the treatment of moderate to severe acne. However, if the patient's condition is special and the skin is too sensitive, special treatments such as sedation and analgesia may be considered [7]. Accurate operation of micro-needle radiofrequency is key to ensuring efficacy. During the treatment process, it is necessary to ensure that the needle remains in the sebaceous follicles, which requires high proficiency in the operator's business skills and ion system operation abilities. Bear bile powder is mostly used in the clinical treatment of neurological diseases and is less commonly used in the treatment of skin diseases such as acne. However, the pharmacological effects of bear bile powder indicate that it has a bitter taste and cold properties, with strong heat-clearing and detoxifying effects. It can be used to treat chronic inflammatory diseases of the follicular sebaceous glands, such as acne vulgaris [8].

Zhai Hanyue et al. studied and verified the effect of microneedle radiofrequency combined with minocycline hydrochloride in the treatment of moderate to severe acne on the face, and believed that the combined treatment had a definite curative effect, high safety, and was worthy of promotion [9]. Hu Huimin et al. believed that the combination of a microneedle radiofrequency acne treatment device and collagen dressing could effectively improve the condition of moderate to severe acne, reduce skin lesion symptoms, and ensure efficacy and safety [10]. Combining the above studies, it can be seen that moderate to severe acne is mostly treated with microneedle radiofrequency and drug combination therapy nowadays, and most patients can obtain satisfactory results. In this study, 80 patients with moderate to severe acne were selected for research and analysis. Compared with microneedle radiofrequency monotherapy, the combined treatment effect of microneedle radiofrequency and bear bile powder was analyzed through a comprehensive analysis of total treatment efficiency, GAGS score, and incidence of adverse reactions. The results showed that the treatment effect and GAGS score of the observation group were better than those of the control group, and the adverse reactions of the two groups were comparable. It can be seen that the combined treatment can exert a synergistic effect, achieve internal and external treatment, so the treatment effectiveness and safety are better, and it is worthy of promotion. However, the effect of microneedle radiofrequency in the treatment of acne has been clinically confirmed, and there are few studies on bear bile powder. Bear bile powder is only effective for acne in some cases, and it is not a specific drug for acne. Therefore, the treatment effect of acne varies with different types and severity of acne, which should be fully considered in clinical practice for the rational use of bear bile powder.

This study has limitations. The observation period for patients was relatively short, and there was a lack of observation indicators, such as recurrence rate. The recent effects and prognosis of combined therapy with micro-needle radiofrequency and bear bile powder have been clinically verified, but the long-term effects of the combined therapy cannot be determined. Based on the current situation, it is necessary to increase the number of patients, extend observation indicators, and add indicators such as recurrence rate to further analyze the effectiveness of combined therapy. Since the patients in this study had moderate and severe acne, and there were individual differences in their conditions, it is recommended to further refine the inclusion criteria for clinical trials, such as comparing and analyzing the combined therapy effects of patients with moderate and severe acne, to provide more detailed data and strong support for clinical treatment options.

5. Conclusion

In summary, the combined application of micro-needle radiofrequency and bear bile powder in the treatment of moderate to severe acne can ensure the effectiveness and safety of the treatment, quickly improve the state of skin lesions, and has significant clinical application value.

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Disclosure statement

The authors declare no conflict of interest.

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