



# Comparison of electrophysiology therapy and glucocorticoid therapy in the treatment of 2 subtypes of vulvar epithelial non-neoplastic lesions: a prospective cohort study

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**Background:** Lichen-like lesions with degeneration and pigmentation alterations can be divided into the following 2 types: (I) chronic simple lichen; and (II) sclerosing lichen. The etiology of the disease is unknown. This study sought to examine the therapeutic effects of electrophysiological smooth-muscle electrical stimulation in the treatment of lichen-like lesions of the vulva.

**Methods:** A total of 80 outpatients, who had been confirmed to have vulvar lichen-like lesions by vulvar biopsy at our hospital from November 2016 to March 2018, were prospectively included in this study. The patients received electrophysiology or glucocorticoid therapy. After completing a treatment cycle according to the clinical treatment routine, the outpatients were monitored at 1-, 3- and 6-month intervals. Patients used an improvement scale (i.e., the patient global impression of change scale) to score their subjective perceptions and subjective symptoms. The clinical curative effect scale was used to calculate the curative effect index and grade the curative effect.

**Results:** After 1 month of treatment, the active enhancement of simple lichen in the electrophysiological treatment group and glucocorticoid treatment group improved, while the active enhancement of simple lichen in the electrophysiological treatment group improved after 3 months of treatment. After 6 months of treatment, the subjective improvement score of the electrophysiological treatment group was better than that of lichen sclerosus. After 3 months of treatment, the effective rate of the electrophysiological therapy group was better than that of the glucocorticoid therapy group. After 6 months of treatment in the electrophysiological treatment group, the efficacy of simple lichen is also better than that of sclerotic lichen.

**Conclusions:** Conventional hormone therapy is easier for patients to accept because of its convenience and low costs.

**Keywords:** Chronic simple lichen; sclerosing lichen; electrophysiology therapy; glucocorticoid therapy

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## Introduction

Vulva lichen-like lesions are long-term diseases that cause degenerations and pigmentation changes in the female vulva. The major symptoms include vulvar pruritus and/or pain, chapped skin, adhesions, and canceration (1). Lichen-like lesions of the vulva can be divided into the simple lichen type and the sclerosing lichen type according to their pathological types. Peri-menopausal females have a higher incidence of the disease, and have an average onset age of 52.6 years (2), but there has been an obvious upward trend in the incidence rate in recent years and also in younger individuals.

The present treatments for lichen-like lesions include drugs, but the effect of drugs on more serious conditions is poor, and surgical treatment may be needed. However, the operation has some disadvantages (e.g., it is painful and recovery is slow), and patients' acceptance of this treatment is low. Progesterone cream/betamethasone cream has been used to treat lichen-like lesions of the vulva for many years, and this cream significantly improves the symptoms of patients in a short time, but patients are still faced with problems, as the disease is difficult to cure and relapse is easy. Thus, there is an urgent need to gather scientific evidence to compare the subjective improvements of symptoms and the treatment effects of various treatment methods.

There are preliminary reports in China on the use of electrophysiological therapy to treat lichen-like lesions of the vulva. This technique uses smooth-muscle electrical

stimulation to slightly and selectively stimulate the smooth muscle of the vascular system and lymphatic system without causing discomfort of the body. It reproduces the action potential of the sympathetic nervous system to maintain or strengthen the basic tension of the smooth muscle to improve the blood circulation and lymphatic circulation of the pelvic cavity as a whole and the vulva. It also improves the local nutritional and immune status to produce a therapeutic effect.

The PHENIX8PLUS study used a pelvic abdominal dynamic therapy apparatus to treat thin endometrial infertility and found that endometrial thickening and endometrial blood perfusion, especially diastolic blood flow, increased after treatment, which suggests that the PHENIX8PLUS pelvic abdominal dynamic therapy apparatus had a significant effect in improving local microcirculation (3). Yeon *et al.* (4) treated 32 patients with the 2 types of lichen-like lesions of the vulva with a pelvic abdominal dynamic therapeutic apparatus, and reported a total effective rate of 93.8% and a cure rate of 18.8%. Lyra *et al.* (5) treated 50 patients with vulvar lichen-like lesions with a pelvic abdominal dynamic therapeutic apparatus and reported a symptom improvement rate of 100%, and an effective rate of 54%. However, the effectiveness evaluation indicators of these studies were not comprehensive or perfect, and no stratified study has been conducted. Thus, the question of whether the therapeutic effects of therapies in patients with different pathological types differ needs to be further clarified, and there is also a lack of comparative studies on the different treatment methods.

This prospective study included patients with the 2 types of vulva lichen-like lesions, who were treated with electrophysiology therapy or glucocorticoid therapy (progesterone cream/betamethasone cream). A subjective symptom improvement scale and curative effect evaluation index were used for the comparative analysis. We present the following article in accordance with the STROBE reporting checklist (available at <https://atm.amegroups.com/article/view/10.21037/atm-23-224/rc>).

## Methods

### Patients

From November 2016 to March 2018, we recruited 98 patients who had vulvar simple lichen or sclerosing lichen (as confirmed by vulvar biopsy) at the Second Hospital of West China of Sichuan University for this study. Patients were excluded from the study if they met any of the following

### Highlight box

#### Key findings

- Conventional hormone therapy is easier for patients to accept because of its convenience and low costs.

#### What is known and what is new?

- Lichen-like lesions with degeneration and pigmentation alterations can be divided into the following 2 types: (I) chronic simple lichen; and (II) sclerosing lichen.
- This study sought to examine the therapeutic effects of electrophysiological smooth-muscle electrical stimulation in the treatment of lichen-like lesions of the vulva, compare its efficacy to that of topical hormones, and explore the differences in the efficacies of the treatments for the different pathological types.

#### What is the implication, and what should change now?

- The treatment strategy should be changed and electrophysiological therapy should be administered to achieve better treatment results and improve the quality of life of the patient.

**Table 1** Baseline characteristics of the patients (mean  $\pm$  standard deviation)

Patients	Electrophysiology therapy (N=40)	Glucocorticoid therapy (N=40)	Statistical value	P
Age (years)	41.43 $\pm$ 11.52	42.09 $\pm$ 10.30	0.38	0.854
Body mass index	22.18 $\pm$ 2.92	22.78 $\pm$ 3.21	0.54	0.511
Course of disease	3.69 $\pm$ 1.58	3.02 $\pm$ 2.66	0.75	0.452
Clinical score before treatment	6.52 $\pm$ 1.41	6.51 $\pm$ 1.61	0.24	0.914

exclusion criteria: (I) were pregnant or had recently expressed a wish to have children; (II) had light sensitivity; (III) had severe medical conditions; and/or (IV) had mental disorders that prevented them from completing the follow-up. Ultimately, 18 patients were excluded from the study based on the above-mentioned exclusion criterion, and 80 patients were entered into the trial. The patients were matched in terms of age, pathological subtype and severity of the disease, and allocated to the electrophysiology therapy group or glucocorticoid therapy group. Each group comprised 80 patients (40 with simple lichen and 40 with sclerosing lichen). Eighty patients were divided into electrophysiological therapy group (N=40) and glucocorticoid therapy group (N=40). In the electrophysiological therapy group, the average age was 41.43 $\pm$ 11.52 years old, and the average age in the glucocorticoid therapy group was 42.09 $\pm$ 10.30 years old. There was no difference in age, body mass index (BMI), course of disease and clinical score before treatment between the two groups ( $P>0.05$ ). The baseline data of the patients are shown in *Table 1*. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by West China Second Hospital ethics committee (No. 20180062). Informed consent was taken from all the patients.

### Treatment methods

#### Electrical stimulation of smooth muscle

The Phenix8 Plus pelvic abdominal dynamic therapeutic apparatus (model: Phenix 8Plus, manufacturer: Electronic Concept Lignon Innovation, France) was used to administer a fat and smooth-muscle stimulation module and pelvic abdominal dynamic therapies using smooth-muscle electrical stimulation technology. Each person received 3 courses of treatment (10 times smooth-muscle electrical stimulation per course).

#### Glucocorticoid therapy

Progesterone cream/betamethasone cream (1 g) was applied

to the affected area in the morning and evening. The progesterone cream was used externally in the morning, and the betamethasone cream was used before the patient went to bed, once a day for 3 months. The patients were instructed to keep their vulvas dry and clean.

### Clinical follow-up and curative effect evaluation index

The curative effect was evaluated using a subjective symptom improvement scale [i.e., the patient global impression of change (PGI-C) scale] (6) and an efficacy evaluation scale (7). The clinical effect is divided into cure, effective and no effect. Cure means that the score of itching symptoms is reduced by 60–90% compared with that before treatment, the skin of the original lesion area becomes normal color, the skin elasticity returns to normal, and there is no recurrence six months after treatment; The effective way is to reduce itching symptoms by 20–50% compared with that before treatment, reduce the area of pale red or white skin, and significantly improve skin elasticity. Ineffective is that vulva pruritus is less than 20% less than before treatment, and skin color is not improved. Total effective rate = (cure number + effective number)/total number of cases  $\times$  100%.

### Statistical analysis

Baseline characteristics are presented as means  $\pm$  standard deviations (SDs) or median [interquartile range (IQR)] for continuous variables, and proportions for categorical variables.

The tendency score matching method was used to analyze only the patients recruited in the center. The propensity score was generated using multivariate logistic regression model. The patients who received electrophysiology or glucocorticoid treatment were dependent variables, and the variables that might affect the treatment effect were covariates, including age, BMI, course of disease, and clinical score before treatment. In order to

estimate the sample size, we established electrophysiological therapy group and glucocorticoid therapy group according to the ratio of 1:1. When the alpha error is 0.05 and the power is 0.8, the number of patients required is 70. In addition, 10 patients were added under uncontrollable circumstances. Therefore, this study requires a sample size of 80 subjects.

SAS 9.3 software was used for the statistical analysis. The measurement data shall be analyzed by one-way ANOVA or *t*-test, otherwise, the rank sum test shall be used. The quantitative data with a normal distribution are presented as the mean  $\pm$  standard deviation. The quantitative data with a non-normal distribution are presented as the median. The *t*-test was used to compare the groups. The disordered classified data were compared using the Chi-square test, and the test level was set as 0.05.  $P < 0.05$  was considered to be statistically significant in the difference between the two groups.

## Results

### *Clinical baseline data of patients*

There were 20 patients with chronic simple lichen and 20 patients with sclerosing lichen in each group. 80 patients were divided into electrophysiological therapy group and glucocorticoid therapy group with 40 members each. *Table 1* shows that there is no difference in age, BMI, course of disease, clinical score before treatment between the two groups ( $P > 0.05$ ), which indicates that they are comparable in general data.

### *Comparison of clinical efficacy*

#### **Subjective symptom improvement scores**

First, we compared the subjective improvement scores of the 2 groups (i.e., the electrophysiological therapy group and the glucocorticoid therapy group) following 1, 3, and 6 months of treatment. The subjective improvement score of the electrophysiological therapy group improved significantly by 35% (14/40), and that of the glucocorticoid therapy group improved by 30% (12/40). The subjective symptoms of all the patients improved from pre-treatment to post-treatment, indicating that the treatment methods were effective. The disease is an easily recurrent disease, and as time went on after treatment, the subjective improvement scores for all the treatment methods gradually decreased. The scores of the electrophysiological therapy group were 14, 12, and 10 at 1, 3 and 6 months after treatment,

respectively, and those of the glucocorticoid therapy group were 12, 9, and 8 at 1, 3 and 6 months after treatment, respectively.

#### **Clinical efficacy scores**

In terms of the curative effect, there was a significant difference between the 2 groups ( $P < 0.05$ ). The total effective rates of the electrophysiological therapy group (77.5%) and the glucocorticoid therapy group (72.5%) were similar. At 3- and 6-month post-therapy, the overall effectiveness rates of the electrophysiological therapy group and the glucocorticoid therapy group decreased, but the overall effectiveness rate of the electrophysiological therapy cohort was greater than that of the glucocorticoid cohort (72.5% *vs.* 57.50% and 67.50% *vs.* 52.50% respectively). The overall effectiveness rate of the glucocorticoid therapy group decreased to 52.5% after 6 months of treatment, while the overall effectiveness of the electrophysiological treatment group decreased to 67.5%, which was greater than that of the glucocorticoid therapy group, but the difference was not statistically significant (*Tables 2-4*). Typical cases are shown in *Figures 1,2*.

### *Comparison of the therapeutic effects of different pathological subtypes*

#### **PGI-C score**

There were 40 cases of 2 pathological subtypes (simple lichen and sclerosing lichen) in each of the 2 groups (the electrophysiological therapy group and the glucocorticoid therapy group). The improvement rate of the former was 80% (16/20), and that of the latter was only 50% (10/20). In the electrophysiological therapy group, the improvement rate of the simple lichen cohort was 60% (12/20), while that of the sclerosing lichen cohort was only 10% (2/20). In the glucocorticoid therapy group, the significant improvement rate of the simple lichen cohort was 50% (10/20), while that of the sclerosing lichen cohort was only 10% (2/20) (*Table 5*).

Significant differences were found in the subjective improvement rates for the 2 pathological subtypes in the electrophysiological therapy group ( $P < 0.05$ ). The subjective improvement rate for the sclerosing lichen cohort was only 30% (6/20). Following 6 months of treatment, the subjective symptom improvement rates differed significantly between the 2 pathological types in the electrophysiological therapy group ( $P < 0.05$ ). The subjective improvement score of the simple lichen cohort was higher than that of the sclerosing lichen cohort in the electrophysiological therapy

**Table 2** Global impression of changed PGI-C scores among the 2 cohorts after 1, 3, and 6 months of treatment

PGI-C	Obvious improvement	Improvement	Slight improvement	No improvement	Total	Statistical value	P
1 month							
Electrophysiology	14	12	9	5	40	0.8893	0.3739
Glucocorticoid	12	10	10	8	40		
3 months							
Electrophysiology	12	10	13	5	40	0.8286	0.4074
Glucocorticoid	9	11	12	8	40		
6 months							
Electrophysiology	10	10	15	5	40	0.5002	0.6170
Glucocorticoid	8	12	12	8	40		

PGI-C, patient global impression of change.

**Table 3** Analysis of the profile of effectiveness scales pre- and post-treatment at 1, 3, and 6 months

Curative effect score	Before treatment	After 1 month of treatment	After 3 months of treatment	After 6 months of treatment
Electrophysiology	6.5±1.4	3.5±2.9	4.0±3.0	4.3±3.5
Glucocorticoid	6.5±1.6	3.8±2.8	4.5±3.5	5.5±3.8

Data are shown as mean ± standard deviation.

**Table 4** The clinical effect among the 2 groups at the end of 1, 3, and 6 months of treatment

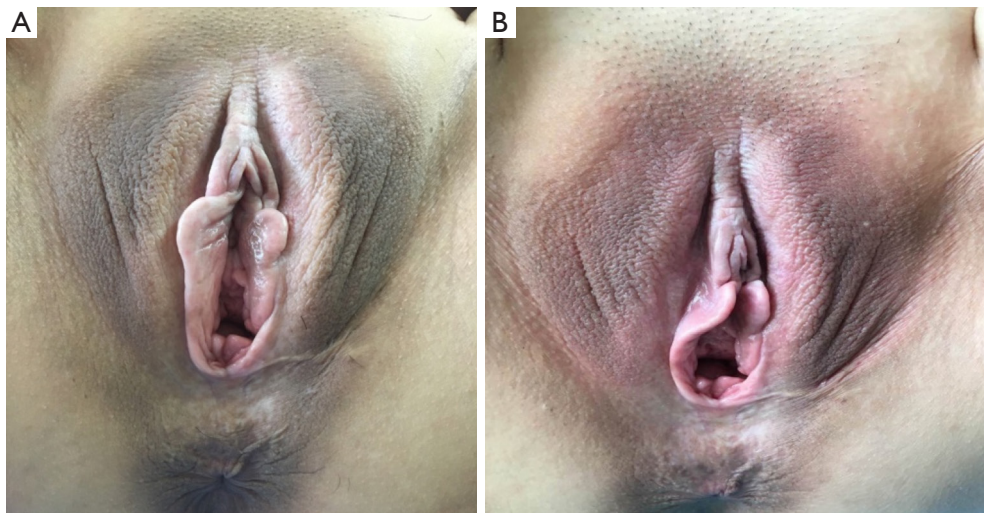
Curative effect score	Cure	Effective	No effect	Efficiency (%)	Total	P
1 month						
Electrophysiology	1	30	9	77.50	40	
Glucocorticoid	1	28	11	72.50	40	0.6291
3 months						
Electrophysiology	1	28	11	72.50	40	
Glucocorticoid	1	22	17	57.50	40	0.1826
6 months						
Electrophysiology	1	26	13	67.50	40	
Glucocorticoid	1	20	19	52.50	40	0.1926

group ( $P < 0.05$ ).

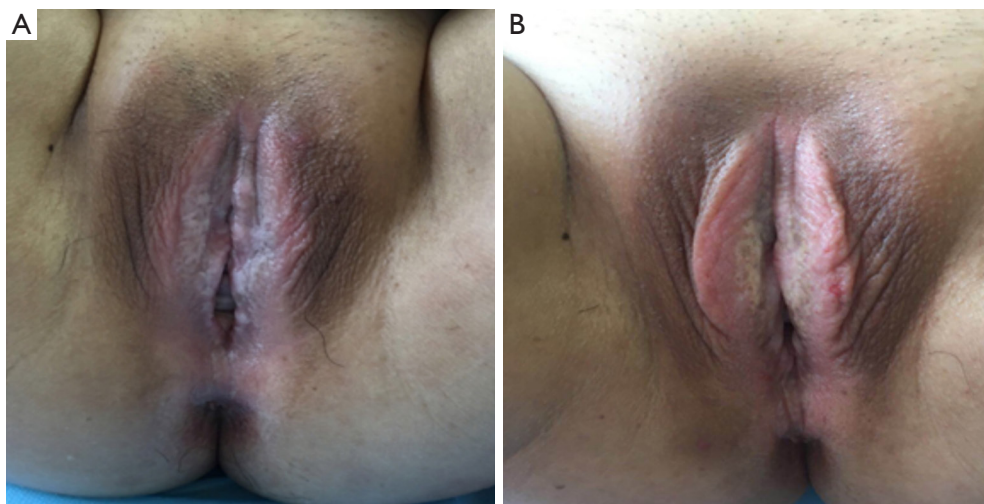
### Comparison of the clinical efficacy of the treatments for different pathological subtypes

After 1 month of treatment, the clinical efficacy between the electrophysiological therapy group and the glucocorticoid therapy group differed significantly ( $P < 0.05$ ). The curative

effect of the simple lichen cohort was better than that of the sclerosing lichen cohort (95% *vs.* 60% and 90% *vs.* 55% for the electrophysiological therapy group and the glucocorticoid therapy group, respectively). The curative effects of the treatments were better for the simple lichen cohort than the sclerosing lichen cohort. The overall effective rate of the electrophysiological therapy group was



**Figure 1** A female aged 45 years with chronic simple lichen before (A) and 3 months after electrical stimulation treatment (B); the vulvar color turned red and the symptoms of self-conscious itching were considerably improved.



**Figure 2** A female patient aged 49 years with a diagnosis of chronic simple lichen (A) before and (B) 3 months after treatment with progesterone/betamethasone cream; the local whitening and damaged part of the vulva gradually turned pink; the itching scale score decreased from 13 points before treatment to 9 points post-treatment; and the itching symptoms improved.

95% (19/20), while that of the sclerosing lichen cohort in the electrophysiological therapy group was 75% (15/20) and 60% (12/20), respectively, and overall effective rate of the glucocorticoid therapy group was only 30% (6/20). After 6 months of treatment, the pathological effects and the efficacy of the electrophysiological therapy and the glucocorticoid therapy differed significantly in terms of the different pathological subtypes. The curative effect for the simple lichen cohort was better than that for the sclerosing

lichen cohort. The effective rate of the sclerosing lichen cohort in the electrophysiological therapy group was 95% (19/20), while that of the electrophysiological therapy group was reduced to 40% (8/20). The specific results are shown in *Table 6*.

## Discussion

The main symptoms of vulvar lichen lesions include vulvar

**Table 5** PGI-C scores between the 2 pathological subtypes at the end of 1, 3, and 6 months of treatment

Group	Subtype	Obvious improvement	Improvement	Slight improvement	No improvement	Total	P
After 1 month of treatment							
Electrophysiology	Simple lichen	12	3	5	0	20	0.0035
	Sclerosing lichen	2	9	4	5	20	
Glucocorticoid	Simple lichen	10	6	3	1	20	0.0007
	Sclerosing lichen	2	4	7	7	20	
After 3 months of treatment							
Electrophysiology	Simple lichen	8	6	4	2	20	0.025
	Sclerosing lichen	4	2	8	6	20	
Glucocorticoid	Simple lichen	9	6	4	1	20	0.1566
	Sclerosing lichen	5	7	5	3	20	
After 6 months of treatment							
Electrophysiology	Simple lichen	8	7	3	2	20	0.0033
	Sclerosing lichen	2	3	9	6	20	
Glucocorticoid	Simple lichen	4	4	7	5	20	0.7551
	Sclerosing lichen	4	2	9	5	20	

PGI-C, patient global impression of change.

**Table 6** Clinical effects for the 2 pathological subtypes after 1, 3, and 6 months of treatment

Group	Subtype	Cure	Effective	No effect	Efficiency (%)	Total	P
After 1 month of treatment							
Electrophysiology	Simple lichen	1	18	1	95.00	20	0.019
	sclerosing lichen	0	12	8	60.00	20	
Glucocorticoid	Simple lichen	1	17	2	90.00	20	0.031
	sclerosing lichen	0	11	9	55.00	20	
After 2 months of treatment							
Electrophysiology	Simple lichen	1	18	1	95.00	20	0.019
	sclerosing lichen	0	12	8	60.00	20	
Glucocorticoid	Simple lichen	1	16	3	85.00	20	0.002
	sclerosing lichen	0	6	14	30.00	20	
After 6 months of treatment							
Electrophysiology	Simple lichen	1	18	1	95.00	20	0.000
	sclerosing lichen	0	8	12	40.00	20	
Glucocorticoid	Simple lichen	1	12	7	60.00	20	0.205
	sclerosing lichen	0	8	12	40.00	20	

pruritus and/or pain, rough vulvar skin, hypopigmentation, chapped skin, atrophy, adhesions, and even canceration. Such symptoms seriously affect the quality of life of patients. In recent years, the patients affected by the disease are becoming younger and younger. Indeed, the youngest patient at our hospital was 7 years old. At present, the pathogenesis of the disease is not clear. Thus, continuous clinical studies are being conducted to explore the pathogenesis and treatment of the disease, but at present, there is no ideal treatment for the disease, which represents a difficult problem for both medical staff and patients.

We conducted a comparative cohort study of 2 different treatments (i.e., electrophysiological stimulation and glucocorticoid therapy) for 2 types of lichen-like lesions of the vulva. Our results suggested the clinical effects of the treatment on the 2 types of lichen-like lesions were good, and the treatments had a total efficiency of >50%.

The total effective rates of electrophysiology and glucocorticoid therapy for the 2 subtypes of vulvar lichen-like lesions after 1 month of treatment were 77.5% and 72.5%, respectively. After 3 and 6 months of therapy, the total effective rates of the electrophysiological and the glucocorticoid therapy groups decreased slightly, but the overall effectiveness rate of the electrophysiological therapy group was greater than that of the glucocorticoid therapy group.

Research has shown that the main ultrastructural changes for the 2 types of lichen-like lesions include a narrowing and decrease in the capillary lumen of the dermis, swelling and the vacuolation of the mitochondria in the cytoplasm of the epidermal cells, a widening of the cell space, and a decrease in the desmosome structure and melanin granules (8). Due to the disorder of cell energy and substance metabolism caused by the disturbance of microcirculation, the activity of tyrosinase in melanosome is affected, and the true melanin (eumelanin) synthesized by tyrosine, dopa, dopamine, and tyroamine decreases, resulting in the hypopigmentation of the diseased skin. This creates great difficulties in the effective treatment of the 2 types of lichen-like lesions (9,10). The local skin microcirculation of the vulva can be improved, the normal state of relaxation and contraction of the arterioles and venules can gradually be adjusted and restored, the blood can be redistributed, and the blood flow can be accelerated. Hemodynamics can improve tissue repair ability by promoting lower limb and pelvic blood circulation and lymphatic circulation, local micro-circulation.

In addition, in terms of clinical efficacy, after 3 months of treatment, the efficacy of the different pathological types in

the electrophysiological therapy group and glucocorticoid therapy group differed significantly, and the curative effect in the simple lichen cohort was better than that in the sclerosing lichen cohort. The effective rate of simple lichen in the electrophysiological therapy group was 95% (19/20, see *Table 6*) after 1 month of treatment, while that of the sclerosing lichen in the electrophysiological group was 60% (12/20,  $P=0.019$ ) (see *Table 6*). After 6 months of treatment, electrophysiological therapy had a better curative effect in the simple lichen cohort than the sclerosing lichen cohort. The effective rate of electrophysiology for the simple lichen cohort was 95%, while that for the sclerosing lichen cohort was 40%. In terms of subjective improvement, the improvement of subjective and clinical efficacy in electrophysiological treatment group was better than that of glucocorticoid therapy group after 1 and 3 months of therapy.

HLADQB10201 can make vulva tissue susceptible to stimulation and promote the occurrence of vulvar diseases (11,12). A decrease in the expression of HLADQB10201 can avoid the onset of vulva diseases; thus, this disorder may be associated with an imbalance in these genes (13). The HLADQB10201 study showed that the HLADQB10201 allele was present in 80% of patients and 41.8% of controls. In short, the reasons for the different responses of the different pathological types to different treatments need to be further studied and explored (14).

This study had some limitations. First, the sample size was small. In a subsequent study, we intend to expand the sample size for an in-depth exploration. Second, the follow-up time for this study was only 6 months, but we will continue to follow-up with the patients to obtain more clinical data to better evaluate the long-term treatment effects. Third, there are few methods for evaluating curative effects, and there is still a lack of standardized guidelines for the treatment of this disease at home and abroad. An expert consensus or clinical guidelines need to be established for the treatment of the disease to provide more authoritative indicators for clinical evaluation.

## Conclusions

In this study, the clinical efficacy and subjective improvement of the 2 treatments for the 2 types of lichen-like lesions of the vulva were compared. We found that the 2 treatments for the vulvar lichen-like lesions achieved better subjective improvement scores in the early stages of treatment. In addition, the different pathological types



responded differently to the treatments. In relation to both the subjective improvement scores and the clinical effect, the electrophysiological response of the simple lichen cohort was better than that of the sclerosing lichen cohort. Conventional hormone therapy is easier for patients to accept because of its convenience and low costs, but our results suggest that when the drug is not effective, the treatment strategy should be changed and electrophysiological therapy should be administered to achieve better treatment results and improve the quality of life of the patient.

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### Footnote

*Reporting Checklist:* The authors have completed the STROBE reporting checklist. Available at <https://atm.amegroups.com/article/view/10.21037/atm-23-224/rc>

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*Conflicts of Interest:* All authors have completed the ICMJE uniform disclosure form (available at <https://atm.amegroups.com/article/view/10.21037/atm-23-224/coif>). The authors have no conflicts of interest to declare.

*Ethical Statement:* The authors are accountable for all aspects of the work in ensuring that questions related to the accuracy or integrity of any part of the work are appropriately investigated and resolved. The study was conducted in accordance with the Declaration of Helsinki (as revised in 2013). The study was approved by West China Second Hospital ethics committee (No. 20180062). Informed consent was taken from all the patients.

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