

# The Pilot Study of Using Traditional Chinese Herbal Ointment to Treat Chronic Vulvar Dystrophy

Yanbing Xiao<sup>1</sup> Qin Xu<sup>2</sup>

Department of gynecology and obstetrics Zunyi medical college Guizhou Zunyi 563003

**Abstract** **Object** to evaluate the clinical effects of Traditional chinese herbal onitment in treating chronic vulvar dystrophy by outside application, and try to explore the possibility of making patent Chinese medicine specially for treatment of chronic vulvar dystrophy. **Methods** 76 cases of chronic vulvar dystrophy were divided into two groups randomly. In test group, 61 cases were treated with the Traditional chinese herbal onitment in sick area of vulva, once a day. 15 cases of control group were treated with 10% cortisone and 2% testosterone ointment, 2~3 times a day, the drug using method is the same as that of the test group. Two groups have the same treatment period of 3~4 months. **Results** the rate of cure, effective and total effectiveness in test group are 85.25%, 13.11% and 98.36% respectively. In control group, the effective and ineffective rates are 66.67% and 33.33% respectively. The differences between two groups are significant ( $p < 0.01$ ). **Conclusion** the effects of Traditional chinese herbal onitment is very prominente to treat chronic vulvar dystrophy, it can not only eliminate the pruritic symptom, but also heal or alleviate the sick area of vulva, with no relapse cases up to now. It's a good and effective method to treat vulvar dystrophy, and deserves further application and researching.

**Key Words** Traditional Chinese herbal ointment; chronic vulvar dystrophy; treatment

Chronic vulvar dystrophy is also called vulvar leukoplakia. It is one of the difficult disease to treat in gynecologic field, and which accompanied with atypical hyperplasia have the potential possibility of carcinomatous change, so it was always been taken as a precancerous lesion of vulva<sup>[1,2]</sup>. The etiological factor, pathogenesis of this disease are not very clear yet now. Therefore, though it has many treatment methods, but its curative effect is poor and recurrence rate is very high<sup>[3]</sup>, up to now it still lack of good treatment method, which is generally accepted. Now that this disease is a kind of chronic illness, and Chinese medicine had showed some advantages in the aspect of treatment<sup>[4-7]</sup>. Thus, it is necessary to explore a special effective drug for this disease based on Chinese medicine theory and previous treatment experience. Form July 1999 to March 2002, our department use self-making Traditional Chinese herbal ointment made by ourselves to treat this disease, only to obtain a good effective result of none individualized treatment of traditional Chinese medicine for vulvar dystrophy. Now report it as follows:

## MATERIAL AND METHODS

### Material

85 cases of chronic vulvar dystrophy patients, which came to our outpatient clinic from July 1999 to March 2002, were definitely diagnosed as "chronic dystrophy of vulva" according to their symptom, sign and vulvar pathology biopsy. During the course of treatment, 9 case were lost, and 76 cases were remained, among

them, the oldest and youngest are 65 and 9 years old respectively, the mean age is  $36.92 \pm 12.04$ . The longest course of diseased is 30 years, the shortest is 1 year, and average disease course is  $7.40 \pm 6.55$ . 6 cases accompanied atypical hyperplasia (AHP), 5 cases are AHP I, 1cases is AHP II. Among 76 cases, just 5 patients have no previous therapy history (6.58%), 71cases remained at least have one treatment experience (93.42%).

### Methods

Grouping 76 cases of patients were divided into two groups according to their diagnosed time, test group has 61cases,while control group has 15 cases. The difference of age, course, pathology and previous therapy history between two groups is not significant. The grouping and pathology of 76 cases show as table 1

### Confecting and using methods of the drug

Choosing high quality Chinese traditional herb such as safflower, glossy privet fruit, Chinese angelica, tuber fleecflower root, malytea scurfpea fruit, tuberculate speranskia herb, solomonseal rhizome, dahurian angeli-

**Table 1** The grouping and pathologic distribution of 76 patients

	hyperplasia	lichen sclerosis	mixed type	sum
test group	41*	13	7	61
control group	11**	3	1	15
Sum	52	16	8	76

\* : 1 AHP II and 4 AHP I are accompanied;

\*\* 1 AHP is accompanied

caroot, costusroot, Szechwan lovge rhizome, Szechwan lovge rhizome, amur corktree bark, borneo camphor, red orpiment et al, mix up and make them insolated, then crush them into very small particles, add proper escipient in the particles to make it become ointment, bottle the herbal ointment for using. Patients in test group wash their vulva with rinsing, after dry, smearing proper herbal ointment on the lesion area before go to bed, medication every day except menstrual phase. Control group was treated with 10% cortisone and 2% testosterone ointment, 2~3/day, the method is the same as that of the test group. The period of treatment in both groups is 3 to 4 month; no other assistant method is used in both groups during the course of treatment.

### Observing index

Recorded the pruritus symptom of all patients and classified its degree before treatment (write down pruritic degree, decided the degree by patient-self). The degree classify of pruritus: degree 0: no any tickle sensation; degree I : gently scratch, abiogenesis and no influence for sleeping; degree II : moderate scratching with sleeping influenced, can still supportability, but usually needs antipruritic drug or sedative agent; degree III : Severe and durative scratching cannot be beared, usually suffer from lack of good sleep and antipruritic drug is necessary.

### Judgment of Curative effect

Cure pruritus disappeared completely and lesion

area of the vulva recovered completely or almost completely.

**Efficiency** pruritus alleviated evidently, lesion area of the vulvar has obvious converse change.

**Inefficiency** no changes happened for symptom and sign after treatment.

**Deteriorate** pruritus and lesion area become more serious after treatment

**Statistical analysis** Redit analysis and u test

## RESULTS

60 cases out of 61 have a good results of itch stopping in test group, among them, 52 patients recovered their sign completely or mostly (Fig1, 2,3), 8 cases alleviated the sign evidently; 1case had a bad effect for stopping itch and non-converse the sign. 4 cases accompany AHP I recovered their pathology after treatment, 1 AHP II (Fig4 pathology number 13884) fade away its symptom and sign after treatment, pathology biopsy show it just have a few inflammation cell exist, no AHP was seen after treat (Fig 5 pathologic number 142644). Up to now, there is no patient relapse in test group. While in control group, 11cases changed their treatment method from cortisone /testosterone ointment into Traditional Chinese herbal ointment due to bad effects or relapse. Total treatment results of 76 cases show as table2, Redit value of different degree for summation data view as table3

**Table 2** the results comparison of 76 cases

group	cure	efficiency	inefficiency	deteriorate	sum
est group	52(85.25%)	(13.11%)	1(1.64%)	0(0.00%)	61
control group	0(0.00%)	10(66.67%)	3(20.00%)	2(13.33%)	15

**Table 3** 76 cases Redit value of different degree for summation data

curative effect degree (1)	test group (2)	control group (3)	sun (4)	(4)/2 (5)	(4) add up moved to next shelf (6)	(5)+(6) (7)	R=(7)/N (8)
deteriorate	0	2	2	1	0	1	0.0132
inefficiency	1	3	4	2	2	4	0.0526
efficiency	8	10	18	9	6	15	0.1975
cure	52	0	52	26	24	50	0.1975
sum	61	15	76(N)				

$$\bar{R}_{\text{test group}}=0.5876$$

$$\bar{R}_{\text{control group}}=0.1439$$

$$u=5.32 \quad p<0.01$$



**Fig.1a** pretherapy:hyperplastic dystrophy, both minor and major labia are dark red, roughness, depigmentation and ulcer formation in some area



**Fig.1b** post-treatment: after 3 month, the appearance, color and luster of both minor and major labia had already recovered



**Fig.2a** pretherapy: mixed dystrophy, in both inside of minor and major labia, skin and mucosa are pale, elasticity is poor and accompanied by rhagas



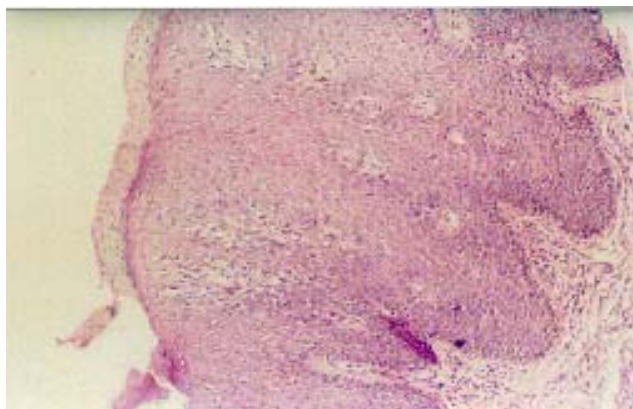
**Fig.2b** post-treatment: after 4 month, the lesion area almost recovered, rhagas disappeared



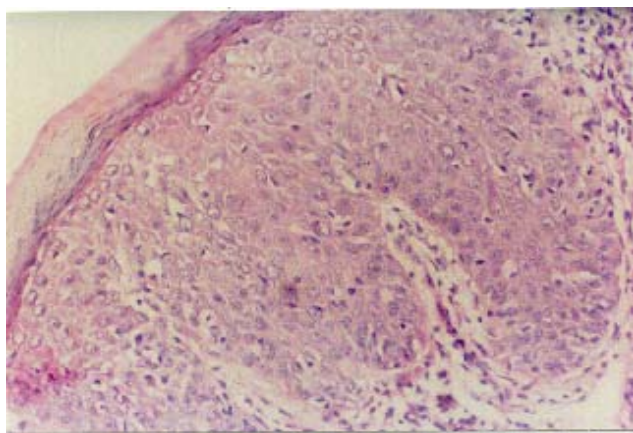
**Fig.3a** pretherapy: lichen sclerosus of dystrophy, both minor, major labia and perineal body are white



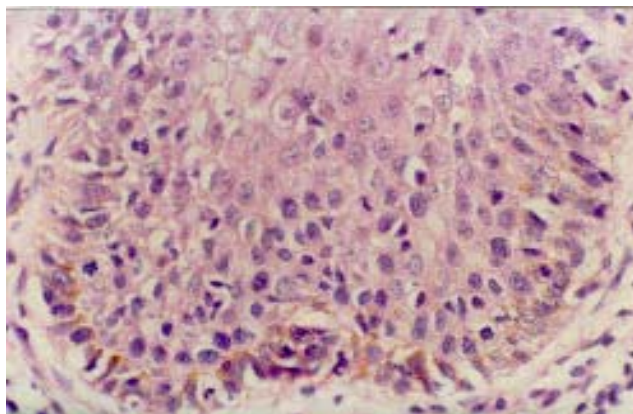
**Fig.3b** post-treatment: after 4months,the color, luster and features of vulva recovered mostly, pigment deposition is evidence

**Fig.4** pretherapy: pathology biopsy of atypical hyperplasia

a. pretherapy (HE: 10×10)



b. pretherapy (HE: 20×10)

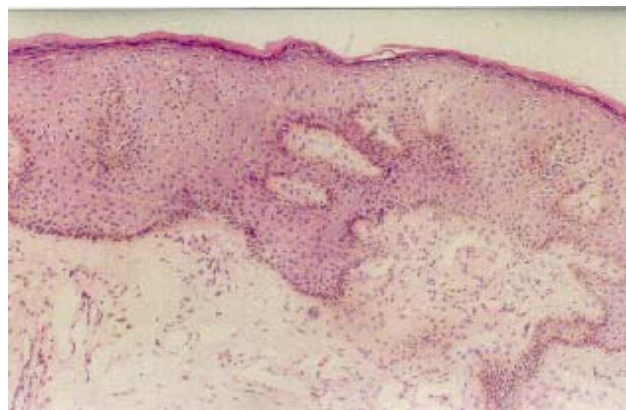


c. pretherapy (HE: 40×10)

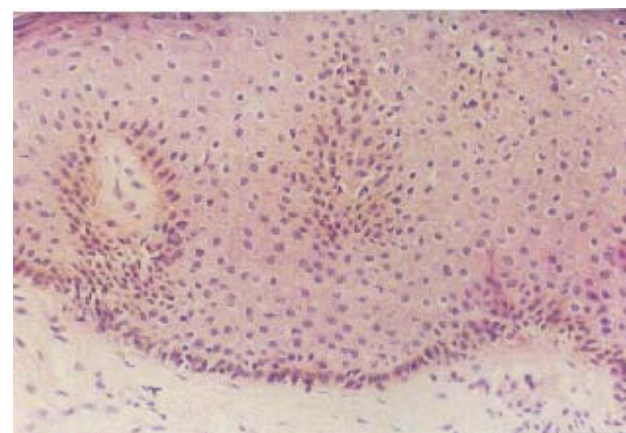
Hyperkeratosis of epidermis, stratum hyperplasia and thickening, echinocyte abnormality partly, size and shape of cell are anomalies, polarity disorders of basal cell, mass lymphocyte exit in superficial dermis

## ***DISCUSSION***

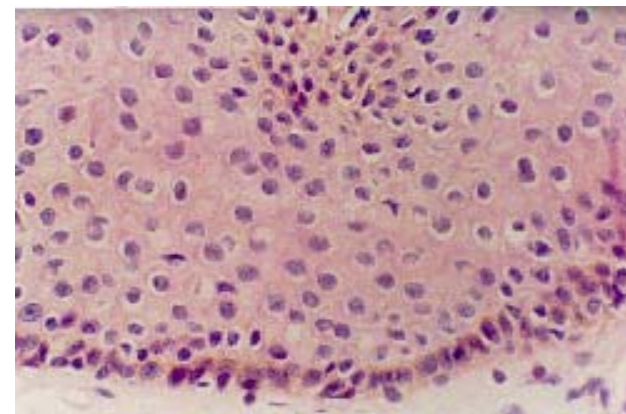
The results show (table1, table2) the rate of cure, effective and total effective in test group are 85.25% ,

**Fig.5** post-treatment: pathology biopsy of atypical hyperplasia

a. post-treatment (HE: 10×10)



b. post-treatment (HE: 20×10)



c. post-treatment (HE: 40×10)

Gently keratinization of epidermis, size and shape of cells are almost normal, polarity of basal cell recovered

13.11%, and 98.36% respectively, no case deteriorate. In the control group, the effective and ineffective rates are 66.67% and 33.33% respectively. The differences between two groups are significant ( $p < 0.01$ ), this shows

the curative effect in test group which use Traditional Chinese herbal ointment is better than that in the control group which use cortisone and testosterone ointment to treat.

Test group has a good effective result of stopping itch symptom after use the herbal ointment 3 to 5 days, the total effective rate is 98.36%, its curative effect was reinforced with medication, not showing evidence in connection with patients' pruritic degree before treatment. 1 case has a bad itch stopping effect which accompany cervical erosion II in this group, this patient had a relatively more leucorrhoea, and this may influenced the herbal ointment to exert its effectiveness, this patient had not finished her course and changed to treat cervical erosion. The recover of the lesion area (sign) in this group general happened at 2 to 3 weeks after treatment. The manifestation is that the lesion area of vulva become dark, resume its elasticity, incrustation and rhagas disappear, shen increasing (Fig1, 2,3). Its curative effect was enhancing with time. 85.25% patients recovered from their symptom and sign completely or almost completely, reaching to the healing criterion regulated by this article. Other 13.11% cases also have evident improvement of their sign. 4 cases AHP I reverse its pathology completely and 1 case AHP II just show a few flame cells exist and no AHP was seen after treatment(Fig1,2).

It is found during in the treatment, the recovery of the sign has something to do with the spot of the lesion; generally speaking, the curative effect is slightly bad in inside part and needs a relatively longer treatment period. But the protruding part has good effects. All this maybe due to the contact time of the drug with the lesion area is longer or shorter

The investigation of this article shows the herbal ointment has a good effect to stop itch symptom and improve lesion signs as well as inversio the pathology of lesion tissue. Maybe this function of inversio pathology is just as its internal reason for good effectiveness. Although for many reasons we cannot re-check all patients' pathology after treatment, especially those Unaccompanied by AHP. But according to analysis from the pathology results of 4 cases AHP I and 1 case AHP II as well as sign improving before and after treatment in test group, it can be concluded that this herbal ointment have the function to improve the lesion tissue to recover. This issue should be specially further studied on cell or even molecule level in the coming days.

The ointment of glucocorticoid (GG) testosterone (TT) is one of the methods to treat chronic vulvar dystrophy that had been widely used in clinic. Its itch stopping effect is not bad in early days, but its effect will

gradually disappear as time goes by, and generally cannot ameliorate lesion sign, it also has the possibility to cause vulvar dystrophy if used for long<sup>[8,9]</sup>. In this article, its rate of symptom remission is 66.67%, without showing evidence function of inversio sign. According to the judging criterion of this article, its summation-healing rate is zero; total accumulative inefficient rate is 33.33%. Therefore, in the long run, GG and TT are not the good and effective methods to treat chronic vulvar dystrophy.

The etiological factor and pathogenesis of chronic vulva dystrophy are not still clear. In western medicine, it is relevant to the stimulation agents of local inflammation or non-inflammation, inheritance factors, autoimmunity and hormone change of whole body or local area<sup>[10,11]</sup>. Recently, some authors<sup>[12,13]</sup> research after it from the view of apoptosis. Chinese medical science classified it in the category of "vulvar itching", and have a relatively perfect theory for its occurrence. They are divided into three cases as follows: gang shen kui sun (deficit of liver and kidney), pi shen yang xu (positive weak of spleen and kidney), shi re yun jie (wet heat accumulation in vulva). As yet in the aspect of treatment is there still a lack of generally accepted method. Western medicine adopts combined therapy, the curative effect is bad and relapse rate is very high, some methods cannot be adopted or continued because patients cannot receive it or its pain is unbearable. Chinese medical science treats it according to the case of different patient; the curative effect is variety and difference with individuals, because it should follow the principle of individualization and lack of special patent medicine. The clinical application of Chinese traditional medicine is restricted.

The herb in this article is a proved recipe, posses the function of "qing re li shi (clear heat and moist), qu fong zhi yang (dispel itching), huo xue hua yu (alive blood and melt silt), qu fu sheng ji (remove decayed tissue and birth flesh)". Its formula and form are relatively fixation, needn't change according to patients and the type of pathology. Its application is very convenient, effects are positive, no poison or side effects had already been found. It accumulated the experience of non-individualized treatment chronic vulva dystrophy with Chinese traditional medicine. If it can enlarge the cases in next stage, and use high flux DNA chip to check the difference of genome express before and after treatment as well as screening the effective components of this herb, also, it is possible to acquire the molecular mechanism of chronic vulva dystrophy and find the attestation in molecular level for the herb's effectiveness to treat this disease. To further creating condition for the commer-

cialization exploitation of this herbal ointment. Therefore, this Traditional Chinese herbal ointment deserves further application and investigation.

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