

Treatment of Vulvitis and Vaginitis

Summary of Clinical Test of Using Yin-Care Lotion for Treatment of Vulvitis and Vaginitis (Stage II) -----Random, Single-blind Control Test Analysis on 115 Cases

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Yin-Care Lotion, produced by Greenline China (former Enwei Pharmaceutical Factory China), is a kind of pure herbal preparation and used for the treatment of vulvitis and vaginitis. In order to evaluate its effectiveness and safety on colpitis mycotica, trichomonal vaginitis, non-specific vulvitis and vaginitis, we present the result of the test as follows according to the replying document about application of clinical study by the Drug Administration Bureau of the Ministry of Health.

Object and method

Those chosen cases from the outpatients in the department of obstetrics and gynecology of our hospital, all of whom with vulvitis and vaginitis belong to the syndrome of damp heat. There were totally 115 cases, among which 60 cases in the therapy group, and 55 cases in the control group. The ages, courses and varieties of diseases and so on are listed as follows in details:

The diagnostic criteria, inclusive and exclusive criteria for case selections; grouping of qualified cases; administration and administration methods for the two groups; observation items and methods; the implementation of the curative effect criteria, judgement of adverse reactions and so on follows the clinical test project formulated by the clinical pharmacological base of Guangzhou University of TCM and approved on the clinical coordination meeting.

Grouping of the cases were carried out based on the simple and randomised principle. The pharmacological base of Guangzhou University of TCM distributed the cards to the patients at random. According to the diagnosis order, the patients were grouped into the therapy group and the control group on the basis of the stipulation including grouping and doctors' advice on those cards of the same serial number distributed at random.

All of the data were used for establishment of a data base through DBASEIII on IBM/PC for the sake of conservancy. POMS (Programme of Medical Statistics) Software can be used for data analysis; the X² inspection for classification data; Ridit analysis for the ranked data; T inspection for the measurement data.

Result

I. Comparability between the therapy group and the control group

1. Age, see Table 1.

Table 1 Comparison in ages between the two groups

	Number of cases	Age
Therapy group	60	29.9±4.9
Control group	55	31.5±8.1

There was no remarkable significance in the discrepancy between the two groups ($P>0.05$)

2. Course, see Table 2

Table 2 Courses of the two groups

	Number of cases	≤7 days	-15 days	-30 days	-90 days	>90 days
Therapy group	51	18	14	7	9	3

Control group	50	15	8	9	14	4
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There was no remarkable significance in the discrepancy of distribution of courses between the two groups. ($P>0.05$)

3. Distribution of disease varieties, see Table 3

Table 3 Distribution of disease varieties in the therapy group and the control group

	Number of cases	Colpitis mycotica	Trichomonal vaginitis	Non-specific vaginitis
Therapy group	60	38	9	13
Control group	55	41	6	8

$X^2=1.69$ $P=0.43$

There was no remarkable significance in the distributing discrepancy in the disease varieties of the two groups. ($P>0.05$)

4. Pre-treatment score of the conditions (the severity of the conditions) including the total score, the score of pruritus vulvae and the score of leukorrhea, see Table 4

Table 4 Comparison in score of the conditions of the two groups

	Number of cases	Pre-treatment total score	Score of pruritus vulvae	Score of leukorrhea
Therapy group	60	25.7±6.8	4.0±1.5	3.7±1.5
Control group	55	24.5±6.1	3.8±1.7	3.8±1.8
T		T=0.993	T=0.670	T=0.325
P		P>0.05	P>0.05	P>0.05

There was remarkable significance in the total scores, the scores of pruritus vulvae and the scores of leukorrhea before the treatment in the two groups ($P>0.05$)

5. Cleaning degree of vagina, see Table 5

Table 5 Cleaning degrees of vaginas of the two groups before the treatment

	Number of cases	Cleaning degree of vagina		
		<II°	<III°	<IV°
Therapy group	60	5	43	12
Control group	55	12	35	8

$X^2=2.58$ $P=0.108$

There was no remarkable significance in the discrepancy of the cleaning degrees of vaginas of the two groups ($P>0.05$).

The result mentioned above showed that there was no remarkable significance in the discrepancy in such factors that would exert influence on curative effect as severity of diseases and cleaning degrees of vaginas, which indicated that the equilibrium and comparability between the two groups were good.

II. Analysis on curative effect

1. Comparison in the general curative effect in the two groups: see Table 6

Table 6 Comparison in the general curative effect in the two groups

	Group	Number of cases	Fully recover	Obviously effective	Effective	Ineffective	
Three days after withdrawal	Therapy group	60	6	35	9	10	$X^2=0.021$
	Control group	55	6	29	13	7	$P=0.884$
Six days after withdrawal	Therapy group	60	25	19	7	9	$X^2=3.64$
	Control group	55	9	28	11	7	$P=0.056$

There was no remarkable significance in the discrepancy of general curative effect of the two groups whatever three days or six days after withdrawal ($P>0.05$). The total curative effect (fully recover + obviously effective + effective) after treatment was 83.33% and 85% respectively three and six days after withdrawal as for the therapy group, and the recovered rate and the obviously effective rate was 68.33% and 73.33% respectively; the general effective rate of the control group was 87.27% and 87.27% respectively; the recovered and obviously effective rates were 63.64% and 67.27%.

2. Improvement of main symptoms, see Table 7

Table 7 Changes in the difference of the scores of main symptoms before and after treatment between the two groups

	Number of cases	Three days after withdrawal	Six days after withdrawal	Pruritus vulvae	Quantity of leukorrhea
Therapy group	60	18.4±10.1	19.9±10.9	2.8±2.1	2.7±2.2
Control group	55	18.0±8.8	17.9±9.0	2.7±1.7	2.8±1.9
t		0.226	1.067	0.279	0.260
p	>0.05	>0.05	>0.05	>0.05	>0.05

There was no remarkable significance in the discrepancy of the scores of the main symptoms, the scores of Pruritus vulvae and the scores of leukorrhea quantities of the two groups three and six days after withdrawal. ($P>0.05$)

3. Rate of turning negative of pathogens, see Table 8.

Table 8 Rate of turning negative of trichomonal, mycotic and other pathogens

	Mycotic pathogen	Trichomonal pathogen	Other pathogens	Total
Therapy group	30/38	7/9	7/10	44/57
Control group	33/41	6/6	8/8	47/55

There was no remarkable significance in the discrepancy of the rates of turning negative of the pathogens in the two groups ($P>0.05$).

III. Adverse reaction

There were not any adverse reactions being found during the course of treatment.

Discussion and conclusion

The results mentioned above showed that there was no remarkable discrepancy in general curative effect, a single symptom, rates of turning negative of pathogens between Yin-Care Lotion as a pure herbal preparation and those specific western medicine such as nysfungin, metronidazole and alficetin. It should be pointed out that Yin-Care Lotion offers the same curative effect as the specific western medicine on curing vulvitis and vaginitis caused by fungus, trichomonad and other pathogenic factors. All of facts have proved the definite curative effect, safety and reliability of Yin-Care Lotion on the treatment of colpitis mycotica, trichomonal vaginitis and non-specific vaginitis.

Typical Case

1. Huang XX, female, 27 years old, married.

Address: No.6, 508, Guang Fu Bei San Yuan, Guangzhou

The patient went to a doctor on September 9, 1992 after having pruritus vulvae for ten days. Monilia was found in the vaginal secretion through the examination, and the cleaning degree of vagina was IIIo, which was diagnosed as colpitis mycotica by western medical science.

The vulva was examined to be swelling, flushing wall of the vagina, moderate quantity of leukorrhea, yellow leukorrhea taking the shape of rotten dregs, red tongue property, yellow and greasy fur and string-like pulse, which can be diagnosed as damp-heat leukorrhea according to TCM. Wash the vulva and vagina with 300ml 10% Yin-Care Lotion, and then make them dry. Wet through a sterilized cotton ball with 50% Yin-Care Lotion, and then put it at the posterior fornix. The examination showed that red swelling of the skin of the vulva, yellow leukorrhea, rotten dregs in leukorrhea, red tongue property, thin and white tongue and string-like pulse disappeared. The result of the re-examination on September 19 showed that there was no monilia being found in the vaginal secretion, and the cleaning degree of vagina was Ilo, with an obvious curative effect. Six days after withdrawal, the patient was examined no pruritus vulvae, no red swelling of the skin, normal colour of leukorrhea, red tongue property, thin and white fur and string-like pulse. The examination on September 22 showed there was no monilia in the vaginal secretion, and the vaginal cleaning degree was Ilo, which was diagnosed as clinical recovery recently.

2. Ren XX, female, 34 years old, married

Address: No. 5, back street, Yue Xiu Nan Dong Yuan, Guangzhou

The patient went to a doctor on September 26, 1992 after pruritus vulvae for half a month. Trichomonad was found in the vaginal secretion through examination, and the cleaning degree of the vagina was IVo, which could be diagnosed as trichomonal vaginitis according to western medical science. The examination showed no red swelling in the vulva, flushing wall of vagina, a large quantity of leukorrhea, yellow and thin leukorrhea mixed with blood, with offensive smell of fish, red tongue property, thin and white fur, slippery pulse, which could be diagnosed as damp-heat leukorrhea according to TCM. Wash the vulva and the vagina with 10% 300ml Yin-Care Lotion, and then make them dry. Wet through a sterilized cotton ball with 50% Yin-Care Lotion, and put in at the posterior fornix. Dressing change and washing once per day, seven days as a course of treatment. Three days after withdrawal, pruritus vulvae of the patient disappeared, and the examination showed that there was no red swelling skin of the vulva, normal wall of vagina, normal and white leukorrhea, no offensive smell of fish, light red tongue properties, thin and white fur and slippery pulse. There was no trichomonad in the vaginal secretion through the re-examination on October 8, and the cleaning degree of the vagina was IVo with an obvious curative effect of Yin-Care Lotion. Six days after withdrawal, the patient had no pruritus vulvae, and the vaginal examination indicated normal, light red tongue property, thin and white fur and slippery pulse. The re-examination was carried out on the vaginal secretion, and trichomonad was not found, and the cleaning degree of the vagina was Ilo, which could be diagnosed as clinical recovery recently.

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