SHORT COURSE TREATMENT OF VAGINAL CANDIDIASIS USING CLOTRIMAZOLE

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Summary

Clotrimazole (Canester®, Gyne-Lotrimin®), a new anti-monilial drug for the treatment of vaginitis due to *Candida albicans,* was submitted to clinical trial in 39 women with primary candidial infection and 44 momen with recurrent candidial infection. Treatment consisted of daily intravaginal insertion of 1 x 0.1 g or 2 x 0.1 g clotrimazole in the form of ovula for 6 days. No oral candidacides were used. Diagnostic smears and cultures were taken from the vagina prior to treatment and within 4 days of medication. Symptoms of discharge, pruritus and abdominal pain were recorded before and after treatment. Thirty-five patients with primary infection (89.9 per cent) were cured using this method of treatment. Patients with recurrent infections were divided into two groups, one receiving 0.1 g clotrimazole once daily and the other receiving it twice daily in conjunction with locally applied clotrimazole ointment. The "success rate" was 75 per cent for the former group and 85 per cent for the latter.

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Introduction

Vaginal discharge and its resulting symptoms are among the most common complaints of women at gynecological outpatient clinics. The condition is usually the result of an infection caused by *Candida albicans.* The liberal use of antibiotics and the introduction of oral contraceptives are significant factors in the increasing susceptibility to candidiasis (Walsh *et al,* 1965). In recent years the incidence of candidiasis has shown a steady rise, affecting about 6% of all gynecological patients (Gardner and Kaufman 1969; Walsh *et al* 1965).

Many therapeutic agents are available, and it has been reported that the "success rate" varies over a wide range (Davis *et al* 1974). However, in view of recurrent infections, probably due to new strains of *Candida,* the spectrum of therapeutic drugs has to be enlarged continuously.

The main requirements in new drugs are: (1) efficiency, (2) minimal side effects, (3) convenient administration.

Material and Methods

One hundred and twenty patients who were referred to the outpatient clinic of the Zahalon Government Hospital, Jaffa, for vulvovaginal candidiasis, participated in a clinical trial using clotrimazole (Canesten®, Gyne-Lotrimin®). Thirty-seven patients failed to follow protocol or

were lost for follow-up and 83 patients were evaluated.

Diagnosis was based on pre-treatment vaginal cultures and subjective symptoms such as discharge, pruritus, and abdominal pains. Meticulous gynecological examinations were performed in each patient, and women with concurrent genital pathology, as well as pregnant women, were excluded from the study. The patients were asked to refrain from sexual intercourse during treatment.

Treatment consisted of intravaginal administration of 0.1 g ovula of clotrimazole over a 6-day period. Patients were divided into 3 groups:

Group 1: Thirty-nine women in whom candidial vaginal infection occurred for the first time. Treatment was administered once daily.

Group 2: Twenty-four women with recurrent vaginal infection due to *Candida*. Treatment was administered once daily.

Group 3: Twenty women with recurrent vaginal infection due to *Candida*. Treatment was administered twice daily, and in addition these women were instructed to apply clotrimazole ointment (Lotrimin^{R}) to the vulva twice daily.

No oral candidacides were used in any of the groups.

During the week after treatment the patients were re-examined, their symptoms recorded, and vaginal cultures obtained. Results of treatment were classified as follows: Patients in whom vaginal culture following treatment was negative for *Candida* and who reported cessation of symptoms were classified as "definitely improved". Patients in whom *either* cessation of symptoms *or* negative vaginal culture occurred were classified as "improved". Patients in whom both symptoms and vaginal infection persisted were classified as "unchanged".

Results

Table I records pretreatment culture

TABLE I

Patient group	1	2	3	Total
Dosage	0.1 g/day	0.1 g/day	2x0.1 g/day + ointment	
Duration of treatment	6 days	6 days	6 days	
No. of patients	39	24	20	83
Pretreatment Culture	No. (%)	No. (%)	No. (%)	No. (%)
Candida	34 (87.2)	18 (75.0)	19 (95)	71 (85.5)
Trichomonas + Candida	1 (2.6)	1 (4.2)	—	2 (2.4)
Bacterial discharge + candida	4 (10.3)	5 (20.8)	1 (5)	10 (12.0)
Pretreatment symptoms				
Discharge	39 (100)	24 (100)	20 (100)	83 (100)
Pruritus	36 (92.3)	23 (95.8)	19 (95)	78 (94)
Abdominal pain	6 (15.4)	4 (16.6)	4 (20)	14 (16.8)
Success rate				
Definitely improved	27 (69.2)	13 (54.2)	16 (80)	56 (67.5)
Improved	8 (20.5)	5 (20.8)	1 (5)	14 (16.8)
Unchanged	4 (10.3)	6 (25.0)	3 (15)	13 (15.6)
Positive results	89.7%	75%	85%	78.9%

findings, pretreatment symptoms, and treatment results in each of the 3 groups.

1. *Efficiency of treatment*

Group 1: In 35 out of 39 patients (89.7%), treatment resulted in "improvement" or "definite improvement". Four patients (10.3%) were classified as "unchanged".

Group 2: In 18 out of 24 patients (75%), treatment resulted in "improvement" or "definite improvement". Six patients (25%) were classified as "unchanged".

Group 3: In 17 out of 20 patients (85%), treatment resulted in "improvement" or "definite improvement". Three patients (15%) were classified as "unchanged".

None of the treated patients showed deterioration following treatment.

2. *Side effects*

Ten randomly selected patients underwent complete blood examination and tests of kidney and liver function, both before and after therapy. No significant changes were found. One patient developed urticaria on both forearms on the fourth day of medication. Although treatment was not discontinued the urticaria disappeared within a day.

No systemic or local side effects were noted.

3. *Convenience of administration*

In comparison with other available forms of therapy, patients found the short 6-day course of treatment very convenient.

Discussion

Results of treatment in this study were well within the range of results reported using other candidacides (Davis *et al,* 1974), Clotrimazole thus sems to be an efficient drug which may safely be added to the spectrum of therapeutic drugs available for the treatment of a disease which occurs eight times more frequently than vaginal trichomoniasis (Gardner and Kaufman, 1969). It has the advantage of convenience, as the treatment period required is short (6 days). Treatment by means of a single daily application of the drug for 6 days produced a lower success rate (75 per cent) in patients with recurrent infection than in those with primary infection (89.7 per cent). Increasing the dossage to two ovula per day for the same time period (Group 3) resulted in a success rate comparable to that obtained in patients with primary infection (Group 1) who were treated with a single daily dose of clotrimazole (85 per cent as compared with 89.7 per cent). Using clotrimazole ointment externally in addition to the intravaginal application seemed to relieve symptoms more rapidly (Brandl, 1976).

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