# Systemic treatment of recurrent candidal vulvovaginitis by Itraconazole

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Summary: 20 women suffering from recurrent candidal vulvovaginitis were treated with Itraconazole, with a single oral dose of 200 mg/day administered after the main meal for three days. The diagnosis was obtained by microscope and culture tests, and check were made 7 and 30 days after completion of the treatment. The symptom score, assessed on the individual patients by means of the classic clinical parameters, showed a significant drop both at the first and second level checks. In our study, the culture tested negative in 75% of cases at the first check, and in 85% of cases at the second check. All patients completed the study without claiming any major side effects.

Key words: Candidal vulvovaginitis; Treatment.

## INTRODUCTION

Since about 65% of women in the 25-50 age group are affected by candidal vulvovaginitis, and almost 50% of them report recurrent infections (3.4 episodes a year) (1) researchers have been striving for a long time to create a safe drug, featuring good complicance and effective coverage against distant recurrences. This resulted in the synthesis of a new broadspectrum triazole antimycotic with a high degree of lipophylic affinity which gives the drug a remarkable affinity with organic tissues. Indeed, at the vulvovaginal level Itraconazole is able to exceed plasmatic concentrations, and also its halflife is longer than ketoconazole's (2, 3, 4); in comparison with the latter, Itracona-

Istituto di Clinica Ginecologica e Ostetrica dell'Università degli Studi di Padova zole is about five times as effective, both in vitro and in vivo  $({}^{5, 6})$ . The mechanism of action of Itraconazole is the same as that of azole-derivated antimycotics  $({}^{7, 8})$ . These act by interfering with the sterol synthesis in the fungal membrane, thereby leading to its massive and rapid cell lysis  $({}^{9, 10})$ . Finally, consistently with the data reported in international literature, the drug proved quicke-acting (both clinically and microbiologically) and welltolerated  $({}^{11, 12})$ .

## MATERIALS AND METHODS

The present study involves outpatient cases, i.e. 20 women suffering from recurrent candidal vulvovaginitis (two or more episodes in the course of the past six months), treated with oral Itraconazole at a dosage of 200 mg/day for three days (a single dose of two 100 mg tablets administered after the main meal). Women with mixed vulvovaginal infections, women who were pregnant or undergoing therapy with topical or oral antimycotics were excluded from the study. Age was in the 18-51 range, body-weight ranged from 45 to 82 kg. 15 women were in their menopause (3 due for

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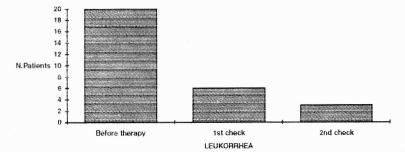
surgery), 5 were taking estroprogestogen contraceptives, one carried an IUD, 2 were obese, suffering from diabetes and on insulin therapy. The diagnosis was reached by means of a fresh microscope examination and confirmed by specific culture tests.

Symptomatic partners were treated with the same therapeutic scheme. The follow-up of the patients included a first check one week after the completion of the treatment and a second check after one month. Response to therapy was assessed by means of a score from 0 to 2 (0 = absent; 1 = medium; 2 = Intense) relevant to the symptoms detected and reported (leukoxanthorrhea, pruritus vulvae, vulvitis, vaginitis).

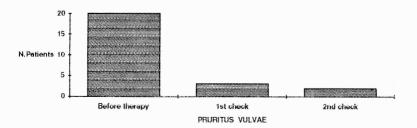
#### RESULTS

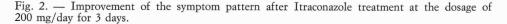
All patients treated with Itraconazole showed a significant regression of subjective symptoms and of physical clinical signs approximately after the fourth day from the start of therapy (average 4.2 days). In particular, 17 women (85%) at the time of their first check (after 7 days) reported the complete disappearance of pruritus vulvae, and 14 of leukorrhea (70%). When checked for the second time (after 30 days) 18 women (90%) reported no more pruritus vulvae and 17 declared that leukorrhea had stopped (85%) (fig. 1 and 2). The clinical signs of inflammation (vulvar and vaginal erythema) were no longer visible at the time of the first check on 16 women (80%) and in 19 (95%) at the time of the second check (fig. 3).

Finally, the microbiological and culture test was negative at the first-level check in 15 cases (75%) and at the second-level check in 17 cases (85%) (fig. 4). None of the women reported remarkable side-effects, so much so that all patients completed the course of therapy.









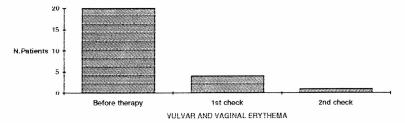


Fig. 3. — Improvement of the clinical signs after Itraconazole treatment at the dosage of 200 mg/day for 3 days.

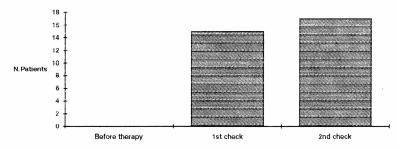


Fig. 4. — Colture negativization after Itraconazole treatment at the dosage of 200 mg/day for 3 days.

### CONCLUSIONS

The numerous pharmacological and clinical experiences made have led us to consider Itraconazole a broad-spectrum antimycotic (<sup>13, 14</sup>) with a high degree of lipophylic affinity (<sup>15</sup>) and tolerability (<sup>16</sup>). Its therapeutic effectiveness is surely the most reassuring feature; and since in this particular instance it showed a global percentage of 85% in the culture negativization and of 85% in the clinical recovery, its values perfectly overlap with the figures of the numerous international trials (85-100% of treated patients) (<sup>17, 18</sup>).

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