COMBINED SYSTEMIC AND TOPICAL TREATMENT OF TRICHOMONIASIS VAGINALIS WITH AZANIDAZOL

M. MARCHIONNI, A. INNOCENTI DEGLI, C. PENNA

Obstetric and Gynecological Clinic, University of Florence (Italy)

SUMMARY

The Authors report the results obtained using Azanidazol on a group of 55 patients affected by Trichomoniasis and studied in the Colposcopic Section of the Obstetric and Gynecological Clinic of the University of Florence. The study was carried out on two groups of patients using two different treatment methods. Complete recovery was reported in 93.4% of the cases in the first group and 100% of those in the second group. Tolerance of the preparation was very high.

Infection due to Trichomonas vaginalis has become an ever-increasing clinical picture in gynecological practice, so much so that the pathology induced by the disease constitutes a socially relevant problem. It is not our intention to discuss the causes of this increased diffusion, as they are amply covered in the literature dealing with the subject ([1, 2, 3, 16]), but rather to talk of our experiences with treatment of the malady.

Our research, about to be published in "Aggiornamenti in Ostetricia e Ginecologia", was conducted on a very large number of women examined through a massive program of cyto-oncological screening, and we discovered a 5.8% incidence of Trichomoniasis ([9]). This percentage is certainly inferior to that of other statistical studies ([5, 7,11, 17]) because the cases considered did not come from a limited group of symptomatic patients who had sought gynecological help for vaginal or genito-urinary disturbances, but rather from a wide cross-section of the population, and we feel we can say that our percentage of incidence of Trichomoniasis comes close to the actual percentage existing in the female population.

Correct treatment of this disease must take account the following criteria:

1) Treatment, whether solely systemic or a combination of systemic and topical, should be as brief as possible.

2) The partner must also be treated systematically, since Trichomonas infection is considered a paravenereal disease ([10, 13, 15]).

3) The drugs used must be well tolerated. Many times other drugs have been the cause of frequent disturbances such as dizziness, urticaria, abdominal cramps, nausea and vomiting ([8, 14]).

4) If possible, substances which are effective against the protozoa but which do not require changes in the patient's eating habits, particularly alcohol consumption, should be used ([12, 14]).

Clin. Exp. Obst. Gyn. - ISSN: 0390 - 6663
VIII, n. 1, 1981

Table 1. — *Patients treated orally with 400 mg/day of Azanidazol and 250 mg/day by vaginal suppository, both for 5 days.*

No. of patients	Results		
	Recovered	Not recovered	Candida infect.
30	28 (93.34%)	2 (6.66%)	1 (3.33%)

5) The effective dose of drugs administered orally should be relatively low, limited to two, or a maximum of three doses a day, since it has been shown that patients refuse a greater number for various reasons.

Up to the present day the use of time-honored trichomonicidal drugs as given good results in spite of various inconveniences ([4, 6, 18]). But in view of the above criteria we have chosen to evaluate the effects and effectiveness of a new preparation, "azanidazol", a 4-[(E)-2-(1-methyl-1H-imidazol-2y1-5-nitro-ethanyl]-2-pirimidine, which has demonstrated a notable anti-Trichomonas effect in previous research studies.

MATERIAL AND METHODS

The research was carried out in the colposcopy section of the Obstetrics and Gynecology Clinic of the University of Florence.

We examined 55 patients during the period between September, 1978, and March, 1979, for whom a diagnosis of Trichomoniasis vaginalis was reached after microscopic examination of fresh vaginal secretions and confirmed by means of slides colored with May-Grunwald-Giemsa stain.

In all the cases colposcopy revealed the presence of the characteristic spots of cervico-vaginitis both after application of 3% acetic acid and after Schiller's test.

Our preferred method of treatment with Azanidazol was to combine topical and systemic administration of the drug. We divided the patients into two groups differring only in the length of treatment; the total dosage of the drug was the same for both groups.

The first group consisted of 30 patients treated as follows:

1) One 200 mg capsule after the two principal daily meals, every day for 5 consecutive days.

2) One 250 mg vaginal suppository in the evening, every day for 5 consecutive days.

The second group consisted of 25 patients treated as follows:

1) One 200 mg capsule after the two principal daily meals, every day for 5 consecutive days.

2) One 250 mg vaginal suppository every 12 hours, for a total of 5 suppositories.

Capsules were also administered to the partners using the same method.

Five days after the end of treatment, vaginal secretions were examined microscopically, and fifteen days after treatment a colposcopy was performed to ascertain the effectiveness of the therapy. We did not set a limit to sexual activity or the amount of alcoholic beverages consumed during the treatment period. Each patient was asked to make note of any collateral manifestations, local or systemic, during the course of treatment.

RESULTS

Table 1 shows the results of treatment in the first group: at the end of therapy Trichomoniasis had disappeared in 28 of the 30 cases examined, a percentage of 93.34%. The two cases of incomplete recovery showed improvement, however, and it should be noted that we could not ascertain whether or no the partners faithfully followed their course of treatment also. Two patients noted gastric disturbances (nausea, pyrosis), and one of these two felt sluggish while taking the medication, but neither one was forced to discontinue treatment. There was only one case of a fungus infection (Candida albicans) as a consequence of the specific therapy for Trichomonas.

Table 2 shows that in the second group all 25 cases of Trichomoniasis vaginalis experienced complete recovery. Only one patient reported gastric disturbances (pyrosis) and sluggishness, but did not re-

Table 2. — *Patients treated orally with 400 mg/day of Azanidazol for 5 days and 5 vaginal suppositories (250 mg each) distributed one every 12 hours.*

No. of patients	Results		
	Recovered	Not recovered	Candida infect.
25	25 (100%)	—	1 (4%)

quire suspension of treatment. There was one case of fungus infection, again Candida albicans, in this group also.

CONCLUSIONS

Based upon our research with 55 patients afflicted by Trichomoniasis vaginalis and treated with combined topical and systemic administration of azanidazol, we can conclude that the drug exerts a notable trichomonicidal effect. This effect is especially significant if we consider the brevity of the treatment period and the fact that we did not advise sexual abstinence in any case in either of the groups.

Choosing between the two treatment methods, we prefer the second (one 200 mg capsule after each principal meal for 5 consecutive days, and five 250 mg vaginal suppositories distributed one every 12 hours) because the intensive local therapy resulted in 100% successful even though the total dosage and the systemic applications were the same in both groups.

Oral administration of the drug did not cause appreciable collateral effects, remembering that we did not prohibit the ingestion of alcoholic beverages.

Concluding the study, then, we maintain that azanidazol demonstrated its effectiveness in the treatment of Trichomoniasis and fulfilled all the prerequisites we consider essential in the proper treatment of this pathological condition.

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