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The Treatment of Trichomonal Vaginitis using Single Dose Tinidazole (Fasigyn-Pfizer)

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SUMMARY

A total of twenty eight patients living in and around the City of Lusaka, Zambia were subjected to a drug trial to determine the effect of a single oral dose of Tinidazole (Fasigyn" Pfizer) in the treatment of Trichomonal Vaginitis. All the twenty eight patients were proven cases of Trichomonal Vaginitis from microscopy of cervical smears. Two grammes of Fasigyn were used as a single oral dose with yeast as Placebo.

Twenty patients were originally treated with Fasigyn and eight received yeast. However two patients in the Fasigyn group absconded, but one later reported satisfactory results. The husbands of two others were untreated. Four patients had other vaginal infections. A microscopic cure rate of 100% and a corrected clinical cure rate of 93.3% was obtained using fasigyn.

The side effects were minimal and the patients themselves regarded them as mild.

INTRODUCTION

Trichomonas Vaginalis, a genito-urinary parasite which is known to be sexually transmitted is now a common gynaecological problem in most clinics. The prevalence rate of this parasite varies in various parts of the world.

The long and tedious course of the drug metronidazole (200 mgs t.i.d orally for a week) proved in our experience to be unsatisfactory as many patients do not complete the full course of treatment.

Workers from various centres have reported on their experiences on the use of a single dose of 2.0 Grammes tinidazole (Fasigyn) in the treatment of Trichomoniasis with very encouraging results; (Aimakhu, 1973; Rosemann and Vaughan, 1973; Mati and Wallace, 1974; 1974; Ongom et al., 1974).

This paper reports the results of a trial which was carried out at the gynaecological clinic of the University Teaching Hospital, Lusaka, using tinidazole in one group of patients and yeast as placebo in the other. During the trial, coitus was not prohibited.

MATERIAL AND METHODS

A total number of twenty eight non-pregnant married women living in and around the City of Lusaka were admitted to the trial. These were patients attending the gynaecological clinic at the University Teaching Hospital for various reasons and were proved to have Trichomonal Vaginitis. Our diagnosis of Trichomoniasis was made by examining microscopially, a cervical and vaginal smear stained by the Papanicolaou method.

A vaginal speculum is used to expose the cervix and an ordinary wooden spatula was used to lightly scrape the ecto-cervix and squamo-columnar junction. This combined pan-cervical and vaginal scrape is immediately spread on a clean glass slide which is then placed in fixative (50 parts of 95% alcohol and 50 parts of Ether) solution for 30 minutes.

The patient's cytology form is completed and the container labelled and passed to the laboratory for processing.

The diagnosis of Trichomonal vaginitis was confirmed in all cases by microscopic examination of the smear.

In addition to the cervical smear, a high vaginal swab was taken for culture and sensitivity in all the twenty eight cases. The patients were than asked to report to the clinic after three days by which time the microscopy results would be ready.

On confirmation of the diagnosis of Trichomonal vaginitis, women admitted to the trial were given a set of paired envelopes each containing four tablets of either two grammes of tinidazole or four yeast tables. The patient was asked to swallow the contents of one envelope with water in the presence of the investigator and instructed to take the other four tablets to the husband to be taken as a single dose.

The patients were seen again after seven days when they were again examined and a repeat smear was taken. Patients with positive smears for Trichomonas Vaginalis were treated three days later with tinidazole 150 mg b.d. for seven days. The same treatment was also prescribed for their husbands.

Other parasitic or fungal infections confirmed from culture results of the High Vaginal Swab were

treated with the appropriate drugs. Any side-effects volunteered or asked for, were noted.

The age of the patients ranged from fifteen to thirty nine. The majority of the patients fell in the age group 25–29 (Table 1). All the patients were married and were living with their husbands during the trial. All twenty eight patients complained of vaginal discharge and pruritus. Two complained of severe dyspareunia and had severe vaginitis. Five patients had been treated for Trichomoniasis before with metronidazole. Two patients had an intrauterine contraceptive device and none was using any oral contraception. Eleven patients had evidence of vaginitis but did not complain of dyspareunia. Eight patients had cervicitis.

TABLE I
AGE GROUP

Age:	15–19	20–24	25–29	30–35	35–39	40+	
No:	4	3	12	5	4	0	

TABLE II
PRESENTING SYMPTOMS

Symptoms:	Discharge	Pruritus	Dyspareunia
No:	28 (100%)	28(100%)	2(7.1%)

TABLE III
CLINICAL SIGNS

Signs:	Offensive Discharge	Unoffensive Discharge	Vaginitis	Cervicitis
No:	21	7	13	8

RESULTS

A breakdown of the patients at the end of the trial showed (Table IV), that twenty patients and husbands had been treated with Fasigyn and Eight had received Placebo (yeast).

TABLE IV
THERAPY

Drug	No.	Symptomatic	Asymptomatic
Fasigyn	20	20	0
Yeast	8	8	0
Total	28	28	0

As seen from Table IV, all the twenty patients who had Fasigyn were symptomatic and all the eight patients who had placebo were also symptomatic.

Of the twenty patients who were treated with fasigyn, eighteen reported for follow-up after the treatment. Of the eighteen patients who did report for follow up, the husband of one patient refused to take the drugs because he did not think that there was anything wrong with him.

One other patient reported having left the first husband and was at the time of follow-up, living with another man who had not received treatment. It is in fact doubtful whether the first husband took the medicine. These two patients had microscopic evidence of Trichomonas Vaginalis at follow-up. It was assumed therefore that they may have been re-infected.

TABLE V
RESULTS OF THERAPY FROM PAP SMEAR

Therapy	No.	-Ve Smear	+Ve Smear	%Cure
Fasigyn	18	16	2	88.8
Yeast	8	0	8	0
Total	26	0	0	0

Assuming that two patients were re-infected, because the husbands were not treated, the microscopic cure rate goes up to 100% in the group of patients who were treated with Fasigyn.

The results of Therapy on the Symptoms is evidenced in Table (VI). Of the eighteen patients treated with Fasigyn, twelve were relieved of vaginal discharge and pruritus. No patient treated with yeast reported any relief from symptoms.

TABLE VI
RELIEF OF SYMPTOMS FROM THERAPY

Symptoms	Drug	No.	Relieved	Percent
Vaginal Discharge	Fasigyn	18	12	66.6
	Yeast	8	0	0
Symptoms	**Drug**	**No.**	**Relieved**	**Percent**
Pruritus	Fasigyn	18	12	66.6
	Yeast	8	0	0

Four of the eighteen patients treated with Fasigyn had other vaginal infections demonstrated by Culture and Sensitivity from the High Vaginal Swab. These included E. Coli, Candida Albicans, and Staphylococcus aureus. These were treated with the appropriate drugs. Excluding the four patients who had demonstrable reasons for vaginal discharge increases

the cure rate in terms of symptoms from 66.6% to 82.8%.

Results were assessed on the basis of symptomatic relief as well as clinical signs and microscopy of the cervical smears. Relief of symptoms together with negative microscopy was defined as a clinical cure and an ABSOLUTE cure, defined as relief of symptoms, signs and a negative microscopy (Tables VII & VIII).

TABLE VII
RESULTS OF THERAPY: (CLINICAL CURE)
CURED OF SYMPTOMS AND MICROSCOPY

Therapy	No.	Cured	% Cured
Fasigyn	18	12	66.6% (corrected 82.2%)
Yeast	8	0	0
Total	26		
Absconded	2		

TABLE VIII
RESULTS OF THERAPY
CURED OF SIGNS, SYMPTOMS AND MICRSCOPY

Therapy	No	Absolute Cure	Percent
Fasigyn	18	12	66.6
Yeast	8	0	0
Total	26		
Absconded	2		

With respect to symptoms and microscopy (Table VII) Twelve of the eighteen patients were cured but when four patients with evidence of other infections are eliminated, the clinical cure rate becomes 82.2% compared with 0% for the patients who received placebo.

Table VIII shows the absolute cure rate to be 66.6%.

Fourteen of the eighteen patients who received fasigyn reported no side effects. Two patients reported slight headaches whereas two patients reported nausea without vomiting. One patient in the yeast group reported nausea.

DISCUSSION

Metronidazole has been used as the traditional treatment for vaginal trichomoniasis ever since it came into the market. The repeated dosage and long drawn out period of treatment (200 mgs t.i.d. for 7 days) however discourages some patients from finishing the full course, hence the frequent recurrence after an apparent cure. (Five patients in our trial had been treated with metronidazole before). This fact has therefore necessitated the search for a single dose regime of treatment for this highly prevalent genital parasite.

Our study shows the efficacy of single oral dose therapy of two grammes tinidazole in the treatment of Trichomonal Vaginitis. One of our two patients who absconded reported later that she did not have the same problems any more. Assuming that she was too cured, both symptomatically and probably microscopically, the clinical cure rate would then go up from 82.2% to 93.3% in the group of patients treated with tinidazole.

A microscopic cure rate of 100% and a clinical cure rate of 93.3% coupled with the simplicity of dosage and minimal side effects would make tinidazole a much more acceptable drug for the treatment of Trichomonal Vaginitis.

The rationale behind our use of the cervical smear in the diagnosis of Trichomonas Vaginalis rather than the simple and quick examination of vaginal secretions was to demonstrate the eradication of the parasites, not only from vaginal secretions, but also from their hidden reservoirs in the cervical and vaginal epithelium. Mati and Wallace (1974) remarked on the difficulty in clinical recognition of trichomonal vaginitis. The characteristics of the discharge did not seem to bear any relations to microscopic findings. This too, has been our experience. It is therefore recommended that trichomonal vaginitis vaginitis should be excluded microscopically rather than clinically. Where there is infection with other organisms, bacterial or fungal, it is advisable to treat with the appropriate therapy.

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