# FLAGYL IN TRICHOMONIASIS (Single Dose Regimen 2 G.)

M. SUBBA RAO\* AND G. S. RAJU;

# Summary and Conclusion

44 married female patients with positive vaginal smears for trichomonas vaginalis were treated with a single oral dose of 'Flagyl' 10 tablets (2 G.). The consorts of the patients also were examined and treated with 10 tablets (2 G.) of 'Flagyl', though their smears were negative for Trichomonas. Side-effects were limited to nausea in one case and mild vomiting in another case.

A striking finding in this trial was the disappearance of trichomonas vaginalis in the vaginal smear right from the second day onwards in 27 cases (50%) after the single oral dose therapy.

All the patients could take the single dose without any difficulty.

The results of this study show the remarkable effectiveness of metronidazole in Trichomonal vaginitis and suggest that the single oral dose of 2 G. is an acceptable treatment for vaginal Trichomoniasis. Since the dosage advocated is half of the standard dosage regimen it is also economical to the patients.

#### Introduction

Trichomonas vaginalis was first described by Donne in 1836.<sup>1</sup> Cosar and Julou<sup>2</sup> found metronidazole to be an effective systemic drug in the treatment of Trichomonas vaginalis infections in woman. Successful treatment of Trichomonas vaginalis with metronidazole (Flagyl) 400 mg. twice daily for five days was reported by McClean<sup>3</sup>.

Csonka<sup>4</sup> in an attempt to simplify the treatment suggested single dose (2 g.) therapy and compared the results with the standard seven days treatment, i.e. 200 mg. thrice daily for seven days.

To overcome the discrepancy between treatment prescribed and that actually

\* Civil Surgeon and Venereologist,

† Tutor in Venereology, Andhra Medical College, Visakhapatnam Received for publication on 8—11—1975 taken, a single dose of metronidazole (2 g. regimen) was tried by Woodcock<sup>5</sup>.

Prompted by the simplicity of therapy and encouraging results reported, a trial with 'Flagyl' (10 tablets) as a single dose was carried out in the outpatient Department of Venereology, King George Hospital, Visakhapatnam.

## Material and Methods

The patients taking part in this trial were attending the Venereology outpatient wing of King George Hospital, Visakhapatnam. 55 female (all married) patients having Trichomonas vaginalis infection were included in this study.

Although culture in Diamond medium was done in a few cases, it was later omitted as it was not considered to be substantially more reliable or more sensitive than simple microscopic examination of the wet film.

Therefore, the presence of trichomonas in all the cases were diagnosed only by wet film examination of vaginal smear.

All the 55 patients along with their consorts were given a single oral dose of 10 tablets (2 g.) of 'Flagyl'. The tablets were taken under the supervision of Medical Officers. The patients were asked to report daily for four days and subsequently on 15th and 30th day for the follow-up examinations.

#### Results

11 patients failed to report for any of the follow up examinations and, therefore, this report pertains to only 44 patients. The patients showing negative vaginal smear should be considered as cured and the end point of the trial achieved.

The vaginal smears of 27 patients who reported during 2 to 4 days period were negative for Trichomonas vaginalis on the second day itself.

The vaginal smears of 14 out of 15 patients were negative for Trichomonas vaginalis from fourth day onwards and in the rest, except one, the smear was negative from the eighth day onwards.

One case (mentioned above) showing positive post-treatment smear for trichomonas vaginalis was considered as treatment failure.

The results of treatment are given in Table 1.

TABLE 1 Results of treatment

|                    | T. vaginalis negative on |        |             |           | · · · · · |
|--------------------|--------------------------|--------|-------------|-----------|-----------|
|                    | 2-4                      | days   | 5-7 days    | 8-10 days | Total     |
| Number<br>patients | of                       | 27*    | 14          | 2         | 43        |
|                    | *n                       | egativ | e on the se | cond day  |           |

#### Discussion

choice for the treatment of trichomonal Reports of success rates vaginitis<sup>6</sup>. with earlier treatments ranging from 30%7 down to 0%8 were followed by reports of 85% to 98% success<sup>9-11</sup>. McClean<sup>3</sup> reported the results of treatment with 400 mg. twice daily for 5 days in 200 women, of whom 198 completed their treatment and underwent at least one examination for cure.

While Csonka's4 work was an attempt to simplify the treatment and then compare the results with the standard dosage regime, Woodcock<sup>5</sup> considered single dose treatment advantageous inasmuch as it reduce the percentage of "treatment failure" likely to result from incomplete and inadequate treatment. In our present series 43 out of 44 patients (97.7%) had complete cure (Table 2) as compared to 82% in the study reported by Csonka (1971)4. The rapid disappearance of trichomonas vaginalis from the vaginal flora in more than 50% of our patients within 2 days was an interesting observation (Table 1). Perhaps if all the patients had co-operated with us by making themselves available for the first follow up, a much higher percentage of disappearance of the parasite during the first follow up period itself could have been achieved.

TABLE 2 Cure Rate

| Total<br>number of | Cui    | red  | Failure |     |
|--------------------|--------|------|---------|-----|
| patients           | Number | %    | Number  | %   |
| 44                 | 43     | 97.7 | 1       | 2.3 |

The above observation would also indicate the continuing high sensitivity of strains of trichomonas vaginalis to metronidazole and agrees with observations of McFadzean et al12 to the non-development of resistance of these strains to metronidazole in spite Since its introduction, metronidazole of its widespread use. The high cure ('Flagyl') has become the drug of rate2 and the rapid excretion rate13

makes metronidazole a safe drug and our present observation also shows that it is effective in large single doses. Tolerance was good and apart from one patient who vomited a few hours after taking the tablets, only one other patient complained of nausea. Since the patient who vomited a few hours after taking the tablets still showed a negtaive smear, it was presumed that there was no considerable loss of drug in the vomitus.

Inadequate absorption of metronidazole or inactivation of metronidazole by vaginal flora<sup>12</sup>,<sup>14</sup> are possible causes of treatment failure. The one "failed" case in our series would probably fit in the above category and, perhaps, a repeat treatment after a study of the vaginal flora was indicated.

## Acknowledgments

We are very much thankful to the Principal, Andhra Medical College, Visakhapatnam and to the Superintendent, King George Hospital, Visakhapatnam for their kind permission to carry out the trial in King George Hospital, Visakhapatnam.

We are also thankful to Messrs. May and Baker (India) Private Ltd., Madras for their generous supply of 'Flagyl' tablets for carrying out this trial and also to their Technical Representative, Mr. N. S. Prabuchandar, other Medical Officers and social workers for their help in this trial.

#### REFERENCES

- Donne (1836) Trichomonas Vaginalis in Pregnancy-The results of Metronidazole Therapy on the mother and child", J Obstet & Gynaec Brit Cwlth, Vol LXVIII: 723, 1961.
- Cosar C and Julou L: Activite De 1
   (Hydroxy-2-Ethyl) 1 Methyl-2-nitro-5-Imidazole visa-vis der Infections experimentales

- Trichomonas annes, Ann Inst Pasteur, 96: 238, 1969.
- Mc Clean AN: Treatment of Trichomoniasis in Female with a 5 day course of Metronidazole ('Flagyl') Brit J vener Dis 37: 36, 1971.
- 4. Csonka CW: Trichomonal Vaginitis treated with one dose of Metronidazole Brit J vener Dis 47:6, 1971.
- 5. Woodcock KR: Treatment of Trichomonal Vaginitis with single oral dose of metronidazole, Brit J vener Dis, 48:65, 1972.
- Durel P, Roiron V, Siboulet A, et al: Essai d'un Antitrichomonas Derive de I Imidazole (8823 R.P.), C. R. Soc franc Gynec, 29: 36, 1959.
- Pearson AC: Treatment of Trichomonas Vaginitis with Terramycin Vaginal Pessaries, J Obstet Gynaec Brit Cwlth, 64: 436, 1957.
- Willcox RR: Treatment of Vaginal Trichomoniasis with 2-Acetylamino-5-Nitrothiazole (Aminitrozole) given orally, Brit J. vener Dis. 33: 115, 1957.
- Csonka CW: Long term aspect of treatment with metronidazole in Trichomonas Vaginalis, Brit J vener Dis, 39: 258, 1963.
- Evans BA and Caterall RD: Nifuratel Compound with Metronidazole in the treatment of Trichomonas vaginitis, Brit med J, 2, 335, 1970.
- Keighley EE: Trichomoniasis in a Closed Community-Efficacy of Metronidazole, B.M.J. 1: 207, 1971.
- Mc Fadzean JA, Pugh IM, Squires SL, et al: Further Observations in strain sensitivity of trichomonas vaginalis to metronidazole, Brit J vener Dis, 45: 161, 1 69.
- Kane PO, Mc Fadzean JA, Squires S, et al: Absorption and excretion of metronidazole Part I Serum concentration and urinary excretion after oral administration, Brit J vener Dis, 37: 273, 1961.
- Nicol CS, Evans AJ, McFadzean JA et al, Inactivation of Metronidazole, Lancet, ii: 441, 1966.