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Original Research

To compare metronidazole and tinidazole in cases of Bacterial vaginosis- A clinical study

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ABSTRACT:

Introduction: Bacterial vaginosis (BV), formerly called non-specific vaginitis, is a polymicrobial disease characterized by reduction in lactobacilli and hydrogen peroxide production, a rise in vaginal pH and overgrowth of BV associated organisms. The present study was conducted to compare metronidazole and tinidazole in cases of Bacterial vaginosis. **Materials & Methods:** The present study was conducted on 90 patients of Bacterial vaginosis. Patients received either tablet metronidazole 500 mg twice daily for 5 days (Group I) and tablet tinidazole 500 mg once daily + one placebo for 5 days (Group II). In all cases, adverse drug reaction and treatment outcome was assessed. **Results:** Age group 18-35 years had 14 patients in group I and 17 in group II, 35-50 years had 20 in group I and 18 in group II and >50 years had 11 in group I and 10 in group II. Complete cure was seen in 17 in group II and 14 in group I, partially cure 18 in group II and 20 in group I and not cure in 11 in group I and 10 in group II. The difference was significant ($P < 0.05$). Nausea/vomiting was seen in 10 in group I and 2 in group II, GI irritation 12 in group and 4 in group II, headache 6 in group I and 1 in group II and metallic taste 23 in group I and 5 in group II. **Conclusion:** Authors found that tinidazole was better as compared to metronidazole in cases of Bacterial vaginosis.

Key words: Bacterial vaginosis, Metronidazole, Tinidazole

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INTRODUCTION

Bacterial vaginosis (BV), formerly called non-specific vaginitis, is a polymicrobial disease characterized by reduction in lactobacilli and hydrogen peroxide production, a rise in vaginal pH and overgrowth of BV associated organisms.¹ These BV associated pathogens are Gardnerella vaginalis, Ureaplasma urealyticum and anaerobes of the genera Peptostreptococcus, Bacteroides, Mobiluncus, Prevotella, Fusobacterium, Veillonella and Eubacterium.²

BV is a clinical condition characterized by a thin, gray/offwhite, homogenous, malodorous adherent vaginal discharge which is more noticeable after intercourse and menses, having pH > 4.5. Fishy odor is noticed on addition of 10% potassium hydroxide to the

vaginal fluid (whiff test), and the presence of clue cells, a few or no lactobacilli, and small number.³

BV treated with nitroimidazoles carries significant positive outcome. Metronidazole, a nitroimidazole antimicrobial agent, has been used in clinical medicine for more than 45 years and currently is the drug of choice for all anaerobic infections. Metronidazole administered either orally or topically according to multiple dose regimen has long been established as a standard treatment of BV, with 77.9% cure rate.⁴ However, necessity to administer the drug for longer duration potentially reduces compliance, thus increasing the risk of incomplete cure and recurrence of BV. Tinidazole is a relatively newer nitroimidazole derivative with greater antimicrobial activity than

metronidazole which was used for the treatment of Trichomonas vaginalis infection.⁵ The present study was conducted to compare metronidazole and tinidazole in cases of Bacterial vaginosis.

MATERIALS & METHODS

The present study was conducted in the department of Pharmacology. It consisted of 90 patients of Bacterial vaginosis. All were informed regarding the study and written consent was obtained. Ethical clearance was taken before starting the study.

RESULTS

Table I Distribution of patients

Parameters	Group I	Group II
Drug	Metronidazole 500 mg	Tinidazole 500 mg once daily
Number	45	45

Table I shows that group I patients were given tablet Metronidazole 500 mg and in group II patients, Tinidazole 500 mg once daily was given. Each group had 45 females.

Table II Age wise distribution of cases

Age group (Years)	Group I	Group II
18-35	14	17
35-50	20	18
>50	11	10

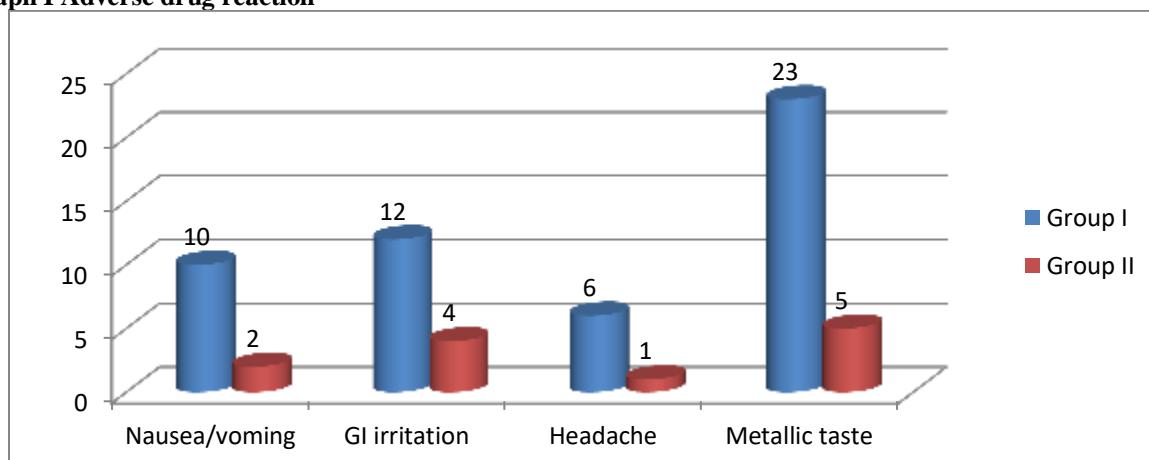
Table II shows that age group 18-35 years had 14 patients in group I and 17 in group II, 35-50 years had 20 in group I and 18 in group II and >50 years had 11 in group I and 10 in group II.

Table III Comparison of cure rates

Cure rates	Group I	Group II	P value
Cure	14	17	
Partially cure	20	18	
Not cure	11	10	0.05

Table III shows that complete cure was seen in 17 in group II and 14 in group I, partially cure 18 in group II and 20 in group I and not cure in 11 in group I and 10 in group II. The difference was significant ($P < 0.05$).

Graph I Adverse drug reaction



Graph I shows that nausea/vomiting was seen in 10 in group I and 2 in group II, GI irritation 12 in group I and 4 in group II, headache 6 in group I and 1 in group II and metallic taste 23 in group I and 5 in group II.

General information such as name, age, etc. was recorded. Patients received either tablet metronidazole 500 mg twice daily for 5 days (Group I) and tablet tinidazole 500 mg once daily + one placebo for 5 days (Group II). Vaginal pH, Whiff test, and Gram stain were done during the follow-up visits. In all cases, adverse drug reaction and treatment outcome was assessed. Results thus obtained were subjected to statistical analysis. P value less than 0.05 was considered significant.

DISCUSSION

In pregnancy, vaginal infections can be associated with drastic complications both to the mother and the neonates, leading to gynaecologic and obstetric complications. BV also increases the risk of acquiring Human Immunodeficiency Virus (HIV) and Sexually Transmitted Diseases (STDs). BV may be considered as Sexually Enhanced Disease (SED) rather than STDs, in which the frequency of intercourse plays a key role. Hence, emphasis to explore primary preventive strategies needs to be given more priority.⁶

Preventive strategies target the risk factors or behaviors for a disease. Studies suggest that BV is associated with a number of risk factors and behaviors, including age, marital status, employment status, occupation, recent antibiotic use, decreased estrogen production of the host, douching, sexual activity, lower age of first intercourse, more frequent episodes of receptive oral sex, spermicide use, STDs, working as a sex worker, smoking, alcohol intake, stress, contraceptives used, frequency of vaginal intercourse, and race/ethnicity. A number of observational studies have reported that women using hormonal contraceptives have a reduced risk of recurrence to BV.⁷ The present study was conducted to compare metronidazole and tinidazole in cases of Bacterial vaginosis.

In present study, group I patients were given tablet Metronidazole 500 mg and in group II patients, Tinidazole 500 mg once daily was given. Each group had 45 females. Age group 18-35 years had 14 patients in group I and 17 in group II, 35-50 years had 20 in group I and 18 in group II and >50 years had 11 in group I and 10 in group II.

Raja et al⁸ conducted a study in which patients diagnosed with BV received either tablet metronidazole 500 mg twice daily for 5 days or tablet tinidazole 500 mg once daily + one placebo for 5 days and instructed to come for follow-up at the 1st week and 4th week. They were categorized as cured, partially cured, and not cured based on Amsel's criteria at the end of the study and compared between two groups. A total 120 women were enrolled in the study, of which 114 completed the study. The treatment arms were comparable. The cure rate with low-dose tinidazole was significantly more compared to metronidazole at 4th week ($P = 0.0013$), but not at 1st week ($P = 0.242$). The adverse drug reactions were less with tinidazole compared to metronidazole.

We found that complete cure was seen in 17 in group II and 14 in group I, partially cure 18 in group II and 20 in group I and not cure in 11 in group I and 10 in group II. Nausea/vomiting was seen in 10 in group I and 2 in group II, GI irritation 12 in group and 4 in group II, headache 6 in group I and 1 in group II and metallic taste 23 in group I and 5 in group II.

Tinidazole has greater and longer antimicrobial activity compared to metronidazole, which is important in preventing recurrence of BV. The BV is associated with reduction in number of vaginal lactobacilli leading to increase in vaginal pH. After treatment, there was reduction in vaginal pH in both groups but to a greater extent with tinidazole. The vaginal pH being the key factor for increased incidence of BV in reproductive age group is better reduced with tinidazole.⁹ Many adjuvant drugs such as ascorbic acid lactobacillus strain and probiotics have been tried to decrease vaginal pH, thereby decreasing the recurrence of BV. Among the study population, most of the patients had adverse drug reactions, of which majority belonged to metronidazole group and few in tinidazole group. The adverse effects were tolerable in both groups. Tinidazole is known for its better side effect profile compared to metronidazole. Many studies have shown similar finding with very few having contradictory findings where they have reported no difference between the drugs in cure rates and tolerability.¹⁰

CONCLUSION

Authors found that tinidazole was better as compared to metronidazole in cases of Bacterial vaginosis.

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