

Original Research

Assessment of efficacy metronidazole and tinidazole in patients with bacterial vaginosis

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Background: Bacterial vaginosis (BV) represents a synergistic polymicrobial syndrome, in which the normal protective lactobacilli are replaced with large quantities of commensal anaerobes. The present study was conducted to compare efficacy and tolerability of oral metronidazole and tinidazole in patients with bacterial vaginosis. **Materials & Methods:** 86 female patients of bacterial vaginosis were divided into 2 groups of 43 each. Group I patients received tablet metronidazole 500 mg twice daily for 5 days and in group II, 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. **Results:** At follow-up at 1st week cure cases were 38 in group I and 40 in group II, partially cured were 5 and 3 and at follow-up at 4th weeks had cure cases in 32 and 36, partially cured in 4 and 7 and not cured in 4 cases in group I. The difference was significant ($P < 0.05$). **Conclusion:** Tinidazole offers a better efficacy than metronidazole in patients with bacterial vaginosis

Key words: Bacterial vaginosis, metronidazole, women

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Corresponding author: Biswadeep Banerjee, Assistant Professor, Department of Pharmacology, Major S D Singh Medical College, Farukhabad, Uttar Pradesh, India**This article may be cited as:** Arora R, Banerjee B. Assessment of efficacy metronidazole and tinidazole in patients with bacterial vaginosis. J Adv Med Dent Sci Res 2019;7(1):210-212.**INTRODUCTION**

Bacterial vaginosis (BV) represents a synergistic polymicrobial syndrome, in which the normal protective lactobacilli are replaced with large quantities of commensal anaerobes (100–1000-fold above normal value) resulting in symptomatic vaginitis in many women.¹ The normal vaginal ecosystem is disrupted resulting in an overgrowth of harmful anaerobic bacteria at the expense of protective bacteria.²

Although the etiology of the clinical syndrome bacterial vaginosis (BV) remains unclear³, it is traditionally described as a vaginal microbial community that lacks lactic acid-producing bacteria, mainly *Lactobacillus* species (spp.), with an overabundance of anaerobic bacteria (including *Gardnerella vaginalis*, *Prevotella* spp., *Mobiluncus* spp., *Ureaplasma urealyticum*, and *Mycoplasma hominis*) and elevated vaginal pH.⁴ There appears to be a host-specific threshold at which the numbers of

specific taxa increase and elicit a host response in the form of vaginal symptoms.⁵ It is hypothesized that vaginal lactobacilli play a critical protective role in the vagina by producing bactericidal and virucidal agents, including lactic acid and bacteriocins, which prevent overgrowth of pathogens and other opportunistic organisms.⁶ The prevalence rate of BV as determined by Gram stain analysis of vaginal fluid ranges from 29% in the United States to >50% in Ugandan villages. Tinidazole is a relatively newer nitroimidazole derivative with greater antimicrobial activity than metronidazole.⁷ The present study was conducted to compare efficacy and tolerability of oral metronidazole and tinidazole in patients with bacterial vaginosis.

MATERIALS & METHODS

The present study comprised of 86 female patients of bacterial vaginosis. The consent was obtained from all enrolled patients.

Data such as name, age etc. was recorded. Patients were divided into 2 groups of 43 each. Group I patients received tablet metronidazole 500 mg twice daily for 5 days and in group II, 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. Data thus obtained were subjected to statistical analysis. P value < 0.05 was considered significant.

RESULTS

Table I Distribution of patients

Groups	Group I	Group II
Drug	metronidazole 500 mg	tinidazole 500 mg
Number	43	43

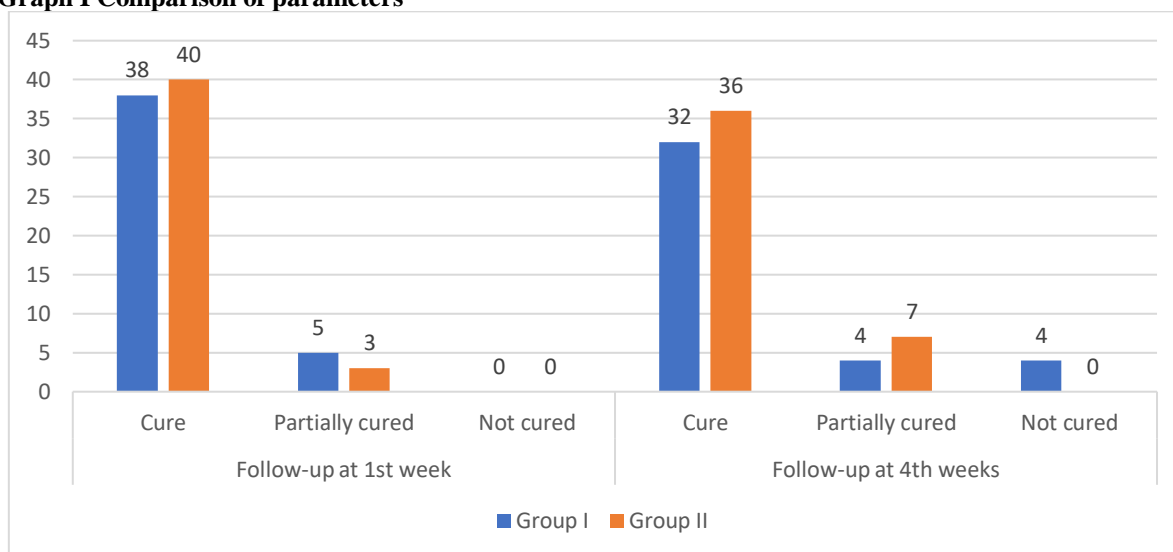
Table I shows that group I patients received tablet metronidazole 500 mg twice daily for 5 days and in group II, tablet tinidazole 500 mg once daily.

Table II Comparison of parameters

Parameters	Variables	Group I	Group II	P value
Follow-up at 1st week	Cure	38	40	0.04
	Partially cured	5	3	
	Not cured	0	0	
Follow-up at 4th weeks	Cure	32	36	0.01
	Partially cured	4	7	
	Not cured	4	0	

Table II, graph I shows that at follow-up at 1st week cure cases were 38 in group I and 40 in group II, partially cured were 5 and 3 and at follow-up at 4th weeks had cure cases in 32 and 36, partially cured in 4 and 7 and not cured in 4 cases in group I. The difference was significant (P< 0.05).

Graph I Comparison of parameters



DISCUSSION

Several longitudinal observational studies have demonstrated that BV or absence of vaginal lactobacilli, as assessed by culture or Gram stain, is an independent risk factor for STIs such as human immunodeficiency virus (HIV), human papillomavirus (HPV), and herpes simplex virus (HSV) infections.^{8,9,10} The present study was conducted to compare efficacy and tolerability of oral metronidazole and tinidazole in patients with bacterial vaginosis.

We found that group I patients received tablet metronidazole 500 mg twice daily for 5 days and in group II, tablet tinidazole 500 mg once

daily. Schwebke et al¹¹ demonstrated in a small randomized trial that treatment and prophylaxis of asymptomatic women with atypical Gram stain smears resulted in a decreased risk for incident chlamydial genital infection compared with that of a group of control women who were under observation. Addition of this new clinical trial evidence to the existing observational studies strongly supports the hypothesis that BV microbiota is causally associated with the acquisition of STIs.

We observed that at follow-up at 1st week cure cases were 38 in group I and 40 in group II, partially cured were 5 and 3 and at follow-up at 4th weeks had cure cases in 32 and 36, partially cured in 4 and 7 and not

cured in 4 cases in group I. Raja et al¹² compared the efficacy and tolerability of oral metronidazole and tinidazole in patients with bacterial vaginosis (BV) using Amsel's criteria. 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. 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.

Larsson et al¹³ found that 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. 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.

CONCLUSION

Authors found that tinidazole offers a better efficacy than metronidazole in patients with Bacterial vaginosis

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