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Original Research Article

A Study to Evaluate the Efficacy of Oral Metronidazole and Tinidazole in the Treatment of Bacterial Vaginosis

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Abstract

Background: Bacterial vaginosis (BV) is a common vaginal infection among women of reproductive age, characterized by alteration of normal vaginal flora. Metronidazole is the standard treatment; however, Tinidazole has emerged as a potential alternative with better tolerability. Comparative evaluation of these drugs is essential for optimal management. The study is aimed to evaluate the efficacy and safety of oral Metronidazole and Tinidazole in the treatment of bacterial vaginosis using Amsel's criteria.

Materials and Methods: This open-label, interventional, comparative study was conducted over one year at a tertiary care hospital in Hyderabad. A total of 100 women diagnosed with BV were randomized into two groups: Group A received oral Metronidazole 500 mg twice daily for 5 days, and Group B received oral Tinidazole 500 mg once daily for 5 days. Patients were followed up at 1st and 4th week. Cure rates were assessed using Amsel's criteria, and adverse effects were recorded. Statistical analysis was performed using Chi-square test with significance set at $p<0.05$.

Results: At 1st week follow-up, cure rates were 40 (83.33%) in the Metronidazole group and 43 (89.58%) in the Tinidazole group ($p>0.05$). At 4th week, cure rates were 34 (70.83%) and 35 (72.91%) respectively ($p>0.05$). Adverse effects, particularly gastrointestinal symptoms, were more frequent in the Metronidazole group, whereas Tinidazole demonstrated better tolerability, though differences were not statistically significant.

Conclusion: Both Metronidazole and Tinidazole are equally effective in the treatment of Bacterial vaginosis, with comparable safety profiles. Although Tinidazole did not demonstrate a statistically significant difference in safety compared to Metronidazole, it may offer advantages in terms of better tolerability, improved patient compliance due to once-daily dosing, and potentially higher cure rates.

Keywords: Bacterial Vaginosis; Metronidazole; Tinidazole; Amsel's Criteria; Treatment Efficacy.

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Introduction

Bacterial vaginosis (BV) is the most common cause of abnormal vaginal discharge among women of reproductive age and represents a significant public health concern worldwide [1]. It is characterized by an imbalance in the normal vaginal flora, with a reduction in hydrogen peroxide–producing lactobacilli and an overgrowth of anaerobic organisms such as Gardnerella vaginalis, Mobiluncus species, and other anaerobes [2].

Clinically, BV presents with homogeneous vaginal discharge, unpleasant odor, and altered vaginal pH [3]. Although often asymptomatic, BV has been associated with adverse reproductive outcomes including preterm labor, pelvic inflammatory disease, and increased susceptibility to sexually transmitted infections [4]. The diagnosis of BV is commonly established using Amsel's criteria, which remains a practical and cost-effective clinical tool in routine practice [5]. These criteria include homogeneous vaginal discharge, vaginal pH greater than 4.5, a positive whiff test, and the presence of clue cells on microscopy [6].

The presence of at least three of these four features confirms the diagnosis. Despite the availability of diagnostic methods, recurrence rates remain high, and optimal treatment strategies continue to be an

area of ongoing research [7]. Metronidazole, a nitroimidazole derivative, has long been considered the standard treatment for BV due to its effectiveness against anaerobic bacteria [8]. However, it is often associated with adverse effects such as gastrointestinal disturbances and metallic taste, which may affect patient compliance [9]. Tinidazole, another nitroimidazole with a longer half-life and potentially better tolerability profile, has emerged as an alternative therapeutic option [10]. Comparative evaluation of these agents is essential to determine their relative efficacy and safety, especially in real-world clinical settings.

Given the high prevalence of BV and the limitations associated with existing therapies, it is important to assess both clinical effectiveness and tolerability of available treatment options. The present study aimed to evaluate the efficacy and safety of oral Metronidazole and Tinidazole in the treatment of bacterial vaginosis using Amsel's criteria in patients attending the Gynaecology outpatient department at Modern Government Maternity Hospital, Nayapul, Hyderabad, and to compare their efficacy and tolerability.

Materials and Methods

This open-label, interventional, comparative study was conducted over a period of one year from June 2018 to June 2019 at Modern Government Maternity Hospital, Nayapul, Hyderabad, in collaboration with the Departments of Pharmacology and Obstetrics and Gynaecology. The study protocol was approved by the Institutional Ethics Committee of Osmania Medical College, Hyderabad.

Women presenting with symptoms of vaginal discharge and diagnosed with bacterial vaginosis (BV) based on Amsel's criteria were enrolled after obtaining written informed consent. A total of 100 eligible patients were recruited and randomly allocated into two equal groups: Group A received oral Metronidazole 500 mg twice daily for 5 days, while Group B received oral Tinidazole 500 mg once daily for 5 days.

The inclusion criteria comprised women aged 15–50 years presenting with white vaginal discharge and confirmed diagnosis of BV, who were willing to participate in the study. Patients were excluded if they had active vaginal bleeding, history of antimicrobial therapy within the preceding 15 days, genital malignancies, or were pregnant or lactating. Baseline demographic details, medical history, and findings from general and gynaecological examination were recorded in a structured case record form prior to initiation of therapy. Under strict aseptic precautions, a high vaginal swab was collected using a sterile cotton swab after insertion of a Cusco's speculum. Diagnosis of BV was established using Amsel's criteria, which included: (i) homogeneous milky white vaginal discharge, (ii) vaginal pH greater than 4.5, (iii) release of fishy odor on addition of 10% potassium hydroxide (whiff test), and (iv) presence of clue cells on microscopic examination. Vaginal pH was assessed using pH indicator strips, while the whiff test was performed by adding KOH to vaginal discharge. Microscopic examination involved saline wet mount preparation followed by Gram staining to identify clue cells. A diagnosis of BV was confirmed when at least three out of four criteria were present.

Patients were followed up at the end of 1st week and 4th week after treatment. During each visit, clinical evaluation was performed along with repeat assessment of Amsel's criteria. Treatment outcomes were categorized as cured (no criteria present), partially cured (two criteria present), and not cured (three or more criteria present). Patients with persistent symptoms at the first follow-up were considered relapse cases and excluded from final analysis at 4 weeks. The primary outcome measure was the proportion of patients achieving complete cure, while the secondary outcome assessed tolerability and adverse drug reactions including gastrointestinal irritation, nausea, metallic taste, and headache.

All collected data were entered into Microsoft Excel and analyzed using Epi Info version 7.2.1.0. Statistical analysis was performed using the Chi-square test to compare cure rates and adverse effects between the two groups. A p-value of less than 0.05 was considered statistically significant.

Results

The study included 100 (70.42%) patients diagnosed with bacterial vaginosis out of 142 screened, who were equally randomized into Group A and Group B with 50 (50.00%) patients each.

The age distribution showed that the majority of patients belonged to the 30–39 years age group, accounting for 24 (48.00%) in Group A and 18 (36.00%) in Group B. Patients aged 20–29 years constituted 11 (22.00%) in Group A and 15 (30.00%) in Group B, while those aged 40–49 years comprised 15 (30.00%) and 17 (34.00%) in Groups A and B, respectively. Overall, both groups were comparable with respect to age distribution (Table 1).

Table 1: Age Distribution of Patients

Age Group (years)	Group A (n=50)	Group B (n=50)
20–29	11 (22.00%)	15 (30.00%)
30–39	24 (48.00%)	18 (36.00%)
40–49	15 (30.00%)	17 (34.00%)
Total	**50 (100%)**	**50 (100%)**

At 1st week follow-up, the cure rate in Group A was 40 (83.33%), while Group B demonstrated a slightly higher cure rate of 43 (89.58%). Partial cure was observed in 1 (2.08%) patient in Group A and 2 (4.17%) patients in Group B. Treatment failure was noted in 7 (14.58%) patients in Group A compared to 3 (6.25%) patients in Group B. Although Group B showed a numerically higher cure rate, the difference between the two groups was not statistically significant (p>0.05) (Figure 1).

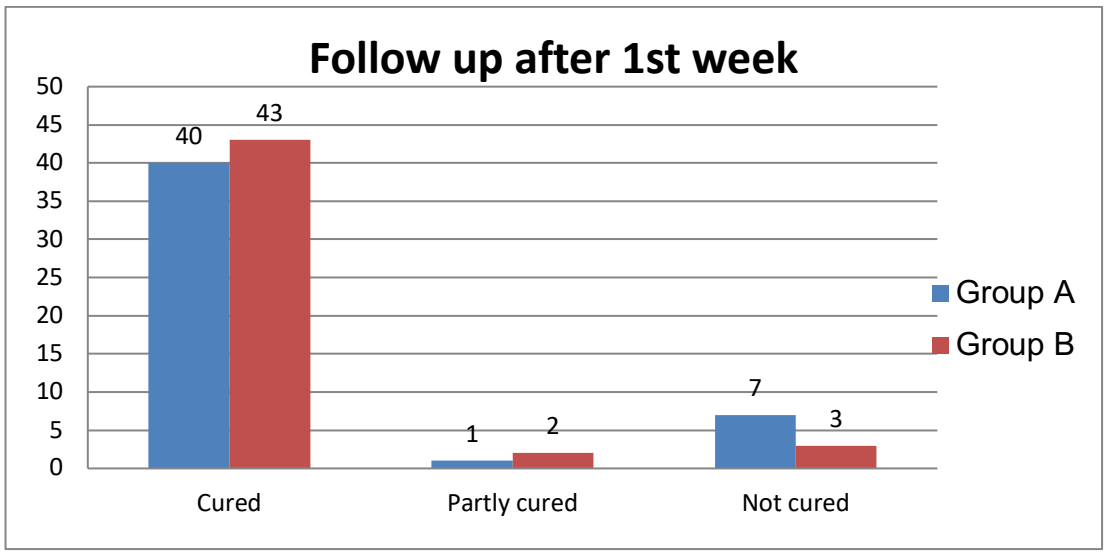

Figure 1: Bar chart showing Cure Rates at 1st Week Follow-up

At 4th week follow-up, a decline in cure rates was observed in both groups. Group A showed a cure rate of 34 (70.83%), while Group B had a comparable cure rate of 35 (72.91%). Partial cure was seen in 2 (4.17%) patients in Group A and 5 (10.42%) patients in Group B. Treatment failure increased to 12 (25.00%) in Group A and 8 (16.67%) in Group B.

Despite minor variations, no statistically significant difference was noted between the two groups at 4 weeks (p>0.05) (Figure 2).

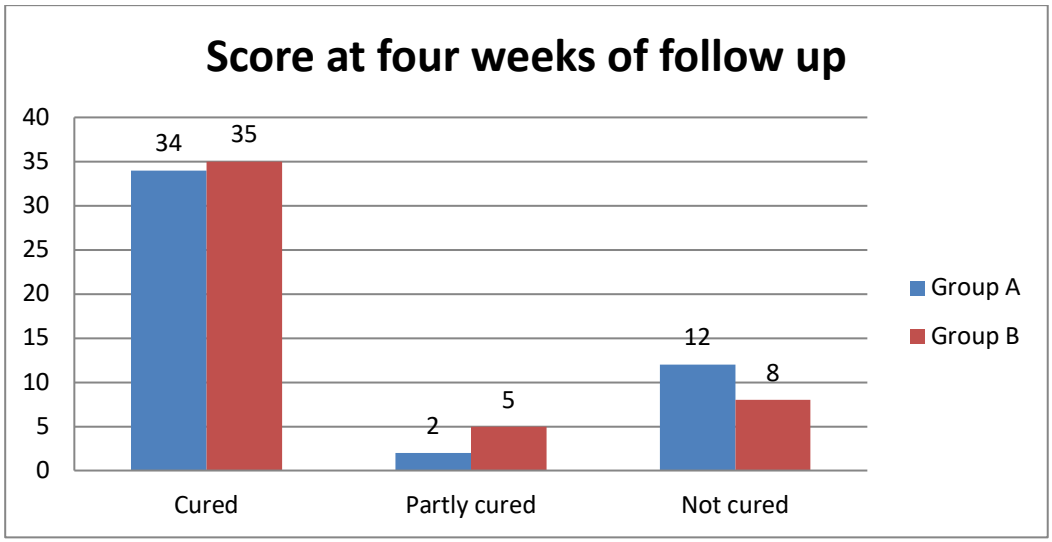

Figure 2: Bar chart showing Cure Rates at 4th Week Follow-up

With regard to safety profile, gastrointestinal adverse effects were the most commonly reported in both groups. GI irritation was observed in 19 (39.58%) patients in Group A compared to 3 (6.25%) in Group B. Similarly, nausea and vomiting were reported in 19 (39.58%) patients in Group A and 5 (10.42%) in Group B. Metallic taste was noted in 18 (37.50%) patients in Group A and 7 (14.58%) in Group B, while headache was reported in 5 (10.42%) and 2 (4.17%) patients in Groups A and B, respectively.

Although adverse effects were numerically higher in the Metronidazole group, the overall difference between the two groups was not statistically significant ($p>0.05$) (Table 2).

Table 2: Incidence of Adverse Effects

Adverse Effect	Group A (n=48)	Group B (n=48)
GI irritation	19 (39.58%)	3 (6.25%)
Nausea/Vomiting	19 (39.58%)	5 (10.42%)
Metallic taste	18 (37.50%)	7 (14.58%)
Headache	5 (10.42%)	2 (4.17%)

Discussion

The present study evaluated the efficacy and safety of oral Metronidazole and Tinidazole in the treatment of bacterial vaginosis using Amsel's criteria. The findings demonstrated that both drugs were effective, with no statistically significant difference in cure rates at both 1st and 4th week follow-ups. At 1 week, cure rates were 83.33% with Metronidazole and 89.58% with Tinidazole, which slightly favoured Tinidazole but without statistical significance.

Similar findings were reported by Raja et al., where cure rates at 1 week were 91.2% for Metronidazole and 96.5% for Tinidazole, again showing no significant difference between the two drugs [11]. These results suggest that both nitroimidazoles are comparably effective in achieving short-term clinical cure.

At the 4th week follow-up, the present study showed cure rates of 70.83% with Metronidazole and 72.91% with Tinidazole, indicating a decline in efficacy over time in both groups, which may reflect recurrence or persistence of infection. Comparable results have been reported in other studies, where long-term cure rates decreased over time. Schwebke et al. reported overall cure rates of 76.8% at 2 weeks and 64.5% at 1 month, with no significant difference between Metronidazole and Tinidazole [12]. Similarly, a randomized controlled trial demonstrated comparable cure rates of approximately 85% for both drugs at early follow-up, with no significant difference at 4 weeks [13]. These findings highlight the challenge of recurrence in BV irrespective of the drug used.

In contrast, some studies have reported slightly better outcomes with Tinidazole, particularly at later follow-up. For instance, a comparative study observed that Tinidazole achieved higher cure rates than Metronidazole at 4 weeks, suggesting a possible advantage due to its longer half-life and better tissue penetration [14]. Another study also reported that Tinidazole had higher cure rates compared to Metronidazole at 4 weeks (84.5% vs 65.7%) [10]. However, these differences have not been consistently observed across all studies. A recent meta-analysis concluded that there is no significant difference between Metronidazole and Tinidazole in terms of efficacy at both early and late follow-up periods, which is in agreement with the findings of the present study [15].

Regarding safety and tolerability, the present study found that gastrointestinal adverse effects such as nausea, vomiting, and metallic taste were more common in the Metronidazole group, whereas Tinidazole showed better tolerability, although the difference was not statistically significant overall. Similar trends have been reported in previous studies, where Tinidazole was associated with fewer adverse effects and better patient compliance [13]. However, large comparative trials have shown no significant difference in adverse event profiles between the two drugs [12]. Thus, while Tinidazole may offer a tolerability advantage in some cases, both drugs are generally well tolerated.

The findings of the present study are consistent with existing literature, indicating that both Metronidazole and Tinidazole are equally effective in the treatment of bacterial vaginosis, with comparable safety profiles. The choice of drug may therefore depend on factors such as patient tolerance, compliance and availability rather than significant differences in efficacy.

Conclusion

The present study demonstrates that both oral Metronidazole andTinidazole are equally effective in the treatment of bacterial vaginosis, with no statistically significant difference in cure rates at both early and late follow-up. Although Tinidazole showed slightly higher cure rates and better tolerability in terms of fewer gastrointestinal adverse effects, these differences were not statistically significant. Both drugs were generally well tolerated and achieved satisfactory clinical outcomes. Therefore, either agent can be used

effectively in the management of bacterial vaginosis, or the choice of therapy may be guided by patient preference, tolerability and availability.

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