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ORIGINAL ARTICLE

Comparison of Vaginal clindamycin and oral metronidazole among patients with bacterial vaginosis

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ABSTRACT:
Background: Bacterial vaginosis (BV) represents a prevalent polymicrobial dysbiosis encountered in premenopausal and postmenopausal women, irrespective of gestational status. The present study was conducted for comparing the clinical efficacy of vaginal clindamycin and oral metronidazole in women diagnosed with bacterial vaginosis. **Materials & methods:**A total of 40 patients with bacterial vaginosis were enrolled and were randomly assigned to receive one of two treatment regimens. One group was administered 100 mg clindamycin ovules intravaginally once daily for three consecutive days, alongside oral placebo capsules taken twice daily for seven days. The comparison group received a total of 500 mg of oral metronidazole per day, in combination with placebo intravaginal ovules used for three consecutive days. The therapeutic outcome was assessed based on clinical parameters, including the presence of a characteristic amine odor in vaginal discharge and the identification of clue cells in microscopic examination, which are diagnostic indicators of bacterial vaginosis. All the results were evaluated. **Results:**The mean age of participants was comparable between the two groups—31.3 years for those receiving clindamycin and 30.9 years for those treated with metronidazole. Cure rates were slightly higher in the oral metronidazole group (70%) than in the vaginal clindamycin group (60%). However, the difference was not statistically significant, as indicated by a p-value of 0.759 and a 95% confidence interval ranging from -9.23 to 12.81, suggesting clinical equivalence in efficacy between both regimens. The clindamycin group reported only one case of local irritation, while no systemic side effects were observed. In contrast, the metronidazole group showed a higher incidence of systemic adverse events, including two cases of nausea/vomiting and one case of taste perversion. This indicates better overall tolerability in the clindamycin group. **Conclusion:**A short-course therapeutic protocol involving intravaginal administration of clindamycin ovules for three consecutive days demonstrated equivalent clinical efficacy in comparison to a seven-day oral regimen of metronidazole at a dosage of 500 mg administered twice daily for the management of bacterial vaginosis.
Key words: Bacterial vaginosis, Clindamycin, Metronidazole

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INTRODUCTION

The equilibrium of the vaginal microenvironment is sustained through intricate immunological and microbial interactions between the host and commensal microbial communities colonizing the vaginal epithelium. In physiologically normal females, the dominant microbial taxa consist primarily of Lactobacillus species, which exert protective roles by inhibiting colonization and proliferation of pathogenic or opportunistic microorganisms. These lactobacilli, particularly those capable of hydrogen peroxide production, contribute to the maintenance of an acidic vaginal pH and support mucosal immunity. Although traditionally characterized by culture-based methods, the application of molecular diagnostics—specifically 16S rRNA gene sequencing—has significantly enhanced microbial profiling, allowing for the identification of previously uncultivable microbial taxa within the vaginal milieu.[1]

Bacterial vaginosis (BV) represents a prevalent polymicrobial dysbiosis encountered in premenopausal and postmenopausal women, irrespective of gestational status. BV is pathognomonically associated with a decline in Lactobacillus spp. and a concomitant rise in microbial diversity, particularly overgrowth of Gardnerella vaginalis, anaerobic Gram-negative bacilli, anaerobic Gram-positive cocci, Mycoplasma hominis, and Mobiluncus spp. The pathophysiology involves enhanced proteolytic enzymatic activity—primarily carboxylases—produced by the overabundant anaerobes. These enzymes metabolize vaginal peptides into volatile biogenic amines such as putrescine, cadaverine, and trimethylamine, which volatilize under elevated pH, resulting in characteristic malodor. Additionally, these metabolic changes induce increased vaginal transudation and exfoliation of squamous epithelial cells, manifesting clinically as a homogenous, malodorous discharge.[2-4]

The clinical implications of BV are substantial. Approximately 40% of idiopathic spontaneous preterm labor and preterm delivery cases are

etiologically linked to BV or similar dysbiotic states lacking protective lactobacilli. Furthermore, BV compromises mucosal barrier function and innate immune defenses, heightening susceptibility to viral and bacterial sexually transmitted infections (STIs), including HIV, Chlamydia trachomatis, Neisseria gonorrhoeae, and Herpes simplex virus type 2. Diagnostic criteria for BV include the clinical parameters of Amsel's criteria or cytological scoring via Nugent's method. First-line pharmacological interventions involve either systemic or topical administration of metronidazole or clindamycin. Nevertheless, longitudinal studies have demonstrated a high recurrence rate, with up to 58% of cases relapsing within one-year post-treatment, underscoring the need for improved therapeutic strategies.[3- 6]Hence; the present study was conducted for comparing the clinical efficacy of vaginal clindamycin and oral metronidazole in women diagnosed with bacterial vaginosis.

MATERIALS & METHODS

The present study was conducted for comparing the clinical efficacy of vaginal clindamycin and oral metronidazole in women diagnosed with bacterial vaginosis. A total of 40 patients with bacterial vaginosis were enrolled and were randomly assigned to receive one of two treatment regimens. One group was administered 100 mg clindamycin ovules intravaginally once daily for three consecutive days, alongside oral placebo capsules taken twice daily for seven days. The comparison group received a total of 500 mg of oral metronidazole per day, in combination with placebo intravaginal ovules used for three consecutive days. The therapeutic outcome was assessed based on clinical parameters, including the presence of a characteristic amine odor in vaginal discharge and the identification of clue cells in microscopic examination, which are diagnostic indicators of bacterial vaginosis. All the results were recorded in Microsoft excel sheet and were subjected to statistical analysis using SPSS software. Chi-square test and student t test were used for evaluation of level of significance.

RESULTS

The mean age of participants was comparable between the two groups—31.3 years for those receiving clindamycin and 30.9 years for those treated with metronidazole. Similarly, the average body mass index (BMI) was 25.3 kg/m² and 26.1 kg/m², respectively. A slightly higher number of patients from rural areas were observed in the metronidazole group (n=9) compared to the clindamycin group (n=7), whereas urban residency was more common among the clindamycin group (n=13 vs. n=11).Cure rates were slightly higher in the oral metronidazole group (70%) than in the vaginal clindamycin group (60%). However, the difference was not statistically significant, as indicated by a p-value of 0.759 and a 95% confidence interval ranging from -9.23 to 12.81, suggesting clinical equivalence in efficacy between both regimens. The clindamycin group reported only one case of local irritation, while no systemic side effects were observed. In contrast, the metronidazole group showed a higher incidence of systemic adverse events, including two cases of nausea/vomiting and one case of taste perversion. This indicates better overall tolerability in the clindamycin group.

Table 1: Demographic data

Variable	Vaginal clindamycin group	Oral metronidazole group
Mean age	31.3 years	30.9 years
Mean BMI (Kg/m^2)	25.3	26.1
Rural residence	7	9
Urban residence	13	11

Table 2: Comparison of outcome

Outcome	Vaginal clindamycin group	Oral metronidazole group
Patients cured	12	14
Cure rate	60	70
95% CI for difference	-9.23 to 12.81	
p-value	0.759	

Table 3: Incidence of complications

Complications	Vaginal clindamycin group	Oral metronidazole group
Local irritation	1	0
Nausea/vomiting	0	2
Taste perversion	0	1

DISCUSSION

Bacterial vaginosis (BV) is a vaginal dysbiosis characterized by a substantial reduction in endogenous hydrogen peroxide-producing Lactobacillus species, accompanied by an overgrowth of polymicrobial anaerobic organisms along the

vaginal epithelium. While often clinically silent, BV constitutes a major cause of symptomatic vaginitis and remains one of the most frequent gynecological complaints prompting women to seek healthcare. In recent years, BV has garnered increasing global attention due to its established correlation with ascending reproductive tract infections and heightened susceptibility to various sexually transmitted infections (STIs).[5- 7] The Centers for Disease Control and Prevention (CDC) currently advocate the administration of antibiotics—specifically oral or intravaginal formulations of metronidazole or clindamycin—as the standard therapeutic regimen for BV. These antimicrobial protocols typically demonstrate high short-term efficacy in symptom resolution. However, long-term outcomes remain suboptimal, with recurrence observed in approximately 50% of treated individuals. As a result, alternative therapeutic strategies are being actively revisited and explored, including the application of topical antiseptics and vaginal disinfectants, with the goal of achieving improved microbial reconstitution and durable remission.[8- 10]Hence; the present study was conducted for comparing the clinical efficacy of vaginal clindamycin and oral metronidazole in women diagnosed with bacterial vaginosis.

The mean age of participants was comparable between the two groups—31.3 years for those receiving clindamycin and 30.9 years for those treated with metronidazole. Similarly, the average body mass index (BMI) was 25.3 kg/m² and 26.1 kg/m², respectively. A slightly higher number of patients from rural areas were observed in the metronidazole group (n=9) compared to the clindamycin group (n=7), whereas urban residency was more common among the clindamycin group (n=13 vs. n=11).Cure rates were slightly higher in the oral metronidazole group (70%) than in the vaginal clindamycin group (60%). However, the difference was not statistically significant, as indicated by a p-value of 0.759 and a 95% confidence interval ranging from -9.23 to 12.81, suggesting clinical equivalence in efficacy between both regimens. Fischbach et al, in a previous study, compared the efficacy and tolerance with 2% clindamycin vaginal cream versus oral metronidazole for the treatment of bacterial vaginosis. Patients were randomly assigned to one of the following two regimens in a 1:1 ratio: clindamycin phosphate vaginal cream 2% (5 g intravaginally at bedtime for 7 days) plus two placebo capsules (twice a day for 7 days) or metronidazole 500 mg (two 250-mg capsules orally twice a day for 7 days) plus placebo vaginal cream (5 g intravaginally at bedtime for 7 days). The patients were seen for follow-up at 5-10 days and 25-39 days after completion of therapy.Seven investigators, four in Germany, two in Austria, and one in Switzerland, enrolled 407 patients. Four patients never received either protocol drug, leaving 403 evaluable for safety. Two hundred thirty-four patients were evaluable for efficacy. The analysis for all evaluable patients showed no significant difference between treatment groups. The cure or improvement rate at 1 month after therapy was 83% in the clindamycin group versus 78% in the metronidazole group. The incidence of drug-related adverse medical events was approximately 12% in both groups.Oral metronidazole and intravaginal clindamycin cream had a similar efficacy of 78 to 83%.[10]

In the present study,the clindamycin group reported only one case of local irritation, while no systemic side effects were observed. In contrast, the metronidazole group showed a higher incidence of systemic adverse events, including two cases of nausea/vomiting and one case of taste perversion. This indicates better overall tolerability in the clindamycin group.In a similar study conducted by Andres et al, authors examined the efficacy of clindamycin vaginal cream for the treatment of bacterial vaginosis. Sixty patients with symptoms of bacterial vaginosis were randomized into the study, and 46 completed the protocol. Twenty-three patients received 2% clindamycin vaginal cream (5 g applied intravaginally at bedtime for 7 days), with placebo oral tablets twice daily for 7 days. The other 23 patients received oral metronidazole tablets (500 mg twice a day for 7 days) and placebo vaginal cream (5 g intravaginally for 7 days). The cure rates for the two regimens were comparable. Twenty-two (97%) of the patients treated with clindamycin vaginal cream had improvement or cure at the first follow-up visit versus 19 (83%) of those taking metronidazole. There was no statistically significant difference between the two results. Side effects for both regimens were comparable. They concluded that 2% clindamycin vaginal cream offers similar efficacy and safety to standard oral metronidazole therapy for bacterial vaginosis.[11] Ferris et al determined the percentage of patients receiving each treatment who developed posttreatment vaginal candidiasis, a potential complication of treating bacterial vaginosis.One hundred one women in whom bacterial vaginosis was diagnosed by standard criteria were randomly assigned to receive: oral metronidazole 500 mg twice daily for 1 week, 0.75% metronidazole vaginal gel 5 g twice daily for 5 days, or 2% clindamycin vaginal cream 5 g once daily for 7 days. Women with coexisting vulvovaginal candidiasis or vaginal trichomoniasis were excluded. Tests of cure by vaginal saline wet prep and potassium hydroxide microscopic examinations, Gram's stain, pH and DNA probe tests for Gardnerella vaginalis and Candida species were scheduled 7 to 14 days following treatment.There were no statistically significant differences in cure rates for oral metronidazole (84.2%), metronidazole vaginal gel (75.0%), or clindamycin vaginal cream (86.2%) (chi 2 = 1.204, df = 2, P = .548) using traditional clinical and laboratory criteria. Cure rates were lower based on DNA testing, indicating that Gardnerella vaginalis may remain after a clinical cure. This would explain cases of recurrent

disease. Posttreatment vulvovaginal candidiasis was experienced by 12.5% of subjects treated with oral metronidazole, 14.8% of subjects treated with clindamycin vaginal cream, and 30.4% of subjects treated with metronidazole vaginal gel.[12]

CONCLUSION

A short-course therapeutic protocol involving intravaginal administration of clindamycin ovules for three consecutive days demonstrated equivalent clinical efficacy in comparison to a seven-day oral regimen of metronidazole at a dosage of 500 mg administered twice daily for the management of bacterial vaginosis. Moreover, the clindamycin ovule formulation exhibited superior tolerability, with a lower incidence of gastrointestinal and systemic adverse effects typically associated with oral nitroimidazole therapy. The localized route of clindamycin delivery not only minimized systemic absorption but also provided targeted antimicrobial action at the site of infection, making it a preferable alternative in terms of patient compliance, tolerability, and clinical outcome in the treatment of bacterial vaginosis.

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