

ORIGINAL ARTICLE

Comparison of Topical and Combined Treatment of Bacterial VaginosisNAILA KHAWER¹, SADAF KASHIF², AMNA ASIF³, SHAGUFTA JABBAR⁴, ZILLE HUMA⁵, FARIHA ARSHAD⁶^{1,3,6}Gynaecologists, ^{4,5}Assistant Professors, Department of Obstetrics & Gynaecology, Social Security Hospital, Lahore²Senior Registrar, Fatima Memorial Hospital LahoreCorrespondence to: Naila Khawer, Email: drnailakhawer@gmail.com, Cell: 0321-9460133**ABSTRACT****Objective:** To compare efficacy of topical clindamycin versus combined effect of metronidazole and clindamycin in bacterial vaginosis patients.**Study Type:** Randomized controlled trial**Place and Duration of Study:** Obstetrics and Gynecology Unit 3, Services hospital, Lahore from 25th January 2018 to 25th July 2018.**Methodology:** Sixty patients fulfilled selection criteria were divided randomly in two study groups. Clindamycin topical application was given to group A and second group was given clindamycin topical treatment plus oral metronidazole. Patients were called in OPD after 2 days and checked for bacterial vaginosis.**Results:** The mean age was 30.35±7.65 years. Twelve (20%) females were nulliparous, 16 (26.7%) had parity 1, 16 (26.7%) had parity 2, 10 (16.7%) had parity 3 and 6 (10%) had parity 4. In clindamycin group, efficacy was achieved in 22 (73.3%) cases while 28 (93.3%) cases in combination group. The difference between both groups was significant ($p<0.05$).**Conclusion:** The combination of clindamycin and metronidazole is more effective in resolution of bacterial vaginosis than clindamycin alone.**Keywords:** Bacterial vaginosis, clindamycin, metronidazole, females, reproductive age**INTRODUCTION**

Bacterial vaginosis (BV) is a clinical condition caused by replacement of the normal hydrogen peroxide producing Lactobacillus species with a sets of aerobic and anaerobic bacteria which causes discharge and foul smell.¹

This disease has been most reliably connected to sexual conduct, and most common cause of this problem is due to sexual contact contaminations.²

Common sign and symptoms include abnormal uterine bleeding followed by abnormal vaginal discharge. It is commonly caused by trichomoniasis, vulvo-vaginal candidiasis and bacterial vaginosis. In BV usually dominant Lactobacilli are replaced by Gardnerella and Mycoplasma Hominis.³

The frequency of this disease in Pakistan is not variable to the global data, in one study it has been estimated that 18-21% of the females are suffering from this problem in our set up.⁴

Bacteria; vaginosis has been related with complications, including upper genital tract disease, preterm labour, and wound contamination. Females undergoing pelvic surgery and pregnant ladies in danger of preterm delivery must be assessed for BV to diminish the rate of medical problems related with this condition. New, more institutionalized criteria for the determination of BV may enhance analytic consistency among clinicians and similarity of study comes about. Utilization of topical treatments in the treatment of BV are effective and related with less symptoms than oral medications.⁵ Reason of pathogenesis is still not understood however, re-infection from sexual partner is might be the reason of recurrence.⁶

There are different treatment modalities being used for the treatment of this problem. Some have used oral, while other has used topical and another group advocated the combined use of metronidazole. It has been seen that the oral metronidazole and the topical use of clindamycin vaginal gel has achieved different cure rates for the treatment of BV. It has been also reported the use of the intravaginal products were found to be more satisfactory. 96.6% cure rate with vaginal Clindamycin as compared to 23% with oral metronidazole.⁷

The combined regime of treatment was better as compared oral and topical, separately. The combined treatment of the patients for bacterial vaginosis was well-tolerated and accepted. 96% of patients were cured with combined treatment^{7,8} and 68% with topical clindamycin alone.⁹

MATERIALS AND METHODS

This randomized clinical trial was conducted at Services hospital, Obstetrics and Gynecology Unit 3, Lahore from 25th January 2018 to 25th July 2018 and comprised 60 cases. All sexually active women of reproductive age (18-45 years old) with foul smelling vaginal discharge diagnosed as a case of BV were included. Already diagnosed diabetics patients, hypertensive patients, secondary disorders (polyps, endometrial hyperplasia, patients on probiotics, even if taken orally, or antibiotics 2 months before recruitment or at any time during the study, pregnant or breast feeding women and patients already on treatment (antibiotic, probiotic, or exogenous hormone treatments) were excluded.

Diagnostic criteria was based on Amsel's Criteria Study Group.¹⁰ Study participants were divided into two groups using lottery method. Group A was given clindamycin topical application once daily for 7 days. Second group was given clindamycin topical treatment for 7 days along with oral metronidazole 400 mg twice daily for 7 days. Patients were called in OPD after 7 days and checked for clinical signs and symptoms. The data was entered and analyzed through SPSS-21. Both groups were compared by using Chi-square test for efficacy and P value ≤ 0.05 considered as significant.

RESULTS

The mean age of patients in clindamycin group was 30.57±7.83 years and 30.13±7.59 years in combination group (Table 1). In clindamycin group, 7 (23.3%) were nulliparous, 8 (26.7%) had parity 1, 6 (20%) had parity 2, 5 (16.7%) had parity 3 and 4 (13.3%) had parity 4. In combination group, 5 (16.7%) females were nulliparous, 8 (26.7%) had parity 1, 10 (33.3%) had parity 2, 5 (16.7%) had parity 3 and 2 (6.7%) had parity 4 (Table 2).

In clindamycin group, 4 (13.3%) were illiterate, 6 (20%) had primary education, 9 (30%) had education up to middle while 11 (36.7%) had education matric or above. In combination group, 4 (13.3%) were illiterate, 11 (36.7%) had primary education, 7 (23.3%) had education up to middle while 8 (26.7%) had education matric or above (Table 3).

In clindamycin group, 9 (30%) belonged to low economic status, 17 (56.7%) belonged to middle class while 4 (13.3%) belonged to high class. In combination group, 16 (53.3%) belonged to low economic status, 11 (36.7%) belonged to middle class while 3 (10%) belonged to high class (Table 4).

In clindamycin group, efficacy was achieved in 22 (73.3%) cases while 8 (26.7%) still had BV symptoms. In combination group, efficacy was achieved in 28 (93.3%) cases while 2 (6.7%)

still had BV symptoms. The difference between both groups was significant ($p < 0.05$) [Table 5].

Table 1: Descriptive statistics of age in both groups

Age (years)	Clindamycin Group	Combination Group
	30.57±7.83	30.13±7.59

Table 2: Distribution of parity in both groups

Parity	Clindamycin Group	Combination Group
0	7 (23.3%)	5 (16.7%)
1	8 (26.7%)	8 (26.7%)
2	6 (20%)	10 (33.3%)
3	5 (16.7%)	5 (16.7%)
4	4 (13.3%)	2 (6.7%)

Table 3: Distribution of education in both groups

Education	Clindamycin Group	Combination Group
Illiterate	4 (13.4%)	4 (13.4%)
Primary	6 (20%)	11 (36.7%)
Middle	9 (30%)	7 (23.3%)
Matric & above	11 (36.7%)	8 (26.7%)

Table 4: Distribution of economic status in both groups

Economic status	Clindamycin Group	Combination Group
Low	9 (30%)	16 (53.3%)
Middle	17 (56.7%)	11 (36.7%)
High	4 (13.3%)	3 (10%)

Table 5: Comparison of efficacy in both groups

Efficacy	Clindamycin Group	Combination Group
Yes	22 (73.3%)	28 (93.3%)
No	8 (26.7%)	2 (6.7%)

$\chi^2 = 4.320$ $P = 0.038$

DISCUSSION

Bacterial vaginosis is a common health problem faced by females and its common symptoms includes abnormal discharge and unpleasant odor. Metronidazole and clindamycin both showed effective results against BV.^{11,12}

In the present study, efficacy of treatment was achieved in 50 (83.3%) cases while in 10 (16.7%) cases, efficacy could not be achieved. In clindamycin group, efficacy was achieved in 22 (73.3%) cases while 8 (26.7%) still had BV symptoms. In combination group, efficacy was achieved in 28 (93.3%) cases while 2 (6.7%) still had BV symptoms. The difference between both groups was significant ($p < 0.05$). In a randomized trial, it was found that 96% of patients were cured with combined treatment⁷ and 68% with topical Clindamycin alone.⁹ Combining the recommended first line therapies of oral metronidazole and vaginal clindamycin, or oral metronidazole with an extended-course of a commercially available vaginal *L. acidophilus* probiotic, does not reduce BV recurrence.¹³

Fischbach et al¹⁴ conducted a study to compare the effectiveness of oral metronidazole and clindamycin vaginal cream for BV treatment and the outcome was same. Cure rate for clindamycin group was 83% whereas it was 78% in metronidazole study group. Both showed same efficacy rate.

Greaves et al¹⁵ reported that 143 women of BV were given clindamycin 300mg and 500mg of metronidazole, both for 7 days. The epidemiology of bacterial vaginosis in relation to sexual behaviour. Almost significant results were obtained in both study groups (6% and 4% respectively). Therefore, it was concluded that, clindamycin is a better and safe option as compared to metronidazole for BV treatment.

CONCLUSION

The combination of clindamycin and metronidazole is more effective in resolution of bacterial vaginosis than clindamycin alone.

REFERENCES

- McGregor JA. Bacterial vaginosis in pregnancy. *Obstet Gynecol Survey* 2000; 55(5):1-19.
- Verstraelen H, Verhelst R, Vaneechoutte M, Temmerman M. The epidemiology of bacterial vaginosis in relation to sexual behaviour. *BMC Infect Dis* 2010;10(1):81.
- Venugopal S, Gopalan K, Devi A, Kavitha A. Epidemiology and clinico-investigative study of organisms causing vaginal discharge. *Indian J Sexually Transmitted Dis* 2017;38(1):69.
- Islam A, Saifdar A, Malik A. Bacterial vaginosis. *JPMA* 2009;59(9):601.
- Carr PL, Felsenstein D, Friedman RH. Evaluation and management of vaginitis. *J General Internal Med* 1998;13(5):335-46.
- Fethers K. Bacterial vaginosis: a riddle, wrapped in a mystery, inside a vagina: the epidemiological and behavioural correlates of bacterial vaginosis disease and key micro-organisms highly specific to bacterial vaginosis 2011.
- Ferris DG, Litaker MS, Woodward L, Mathis D, Hendrich J. Treatment of bacterial vaginosis: a comparison of oral metronidazole, metronidazole vaginal gel, and clindamycin vaginal cream. *J Fam Prac* 1995;41(5):443-50.
- Plummer EL, Vodstrcil LA, Danielewski JA, Murray GL, Fairley CK, Garland SM, et al. Combined oral and topical antimicrobial therapy for male partners of women with bacterial vaginosis: Acceptability, tolerability and impact on the genital microbiota of couples - a pilot study. *PLoS one* 2018;13(1):e0190199.
- Paavonen J, Mangioni C, Martin MA, Wajszczuk CP. Vaginal clindamycin and oral metronidazole for bacterial vaginosis: a randomized trial. *Obstet Gynecol* 2000; 96(2): 256-60.
- Mohammadzadeh F, Dolatian M, Jorjani M, Majd HA. Diagnostic value of Amsel's clinical criteria for diagnosis of bacterial vaginosis. *Global J Health Sci* 2015;7(3):8.
- McDonald HM, Brocklehurst P, Gordon A. Antibiotics for treating bacterial vaginosis in pregnancy. *Cochrane Database Syst Rev* 2007; 1(1).
- Oduyebo OO, Anorlu RI, Ogunsola FT. The effects of antimicrobial therapy on bacterial vaginosis in non-pregnant women. *Cochrane Database Syst Rev* 2006;3.
- Bradshaw CS, Pirotta M, De Guingand D, Hocking JS, Morton AN, Garland SM, et al. Efficacy of oral metronidazole with vaginal clindamycin or vaginal probiotic for bacterial vaginosis: randomised placebo-controlled double-blind trial. *PLoS One* 2012;7(4):e34540.
- Fischbach F, Petersen EE, Weissenbacher ER, Martius J, Hosmann J, Mayer H. Efficacy of clindamycin vaginal cream versus oral metronidazole in the treatment of bacterial vaginosis. *Obstet Gynecol* 1993;82(3):405-10.
- Greaves WL, Chungafung J, Morris B, Haile A, Townsend JL. Clindamycin versus metronidazole in the treatment of bacterial vaginosis. *Obstet Gynecol* 1988;72(5):799-802