

Comparison of Efficacy of 2% Clindamycin Vaginal Cream and Oral Metronidazole for Management of Bacterial Vaginosis in Non-Pregnant Females

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Clindamycin
Vaginal Cream
and Oral
Metronidazole
for Vaginosis in
Non-Pregnant

ABSTRACT

Objective: To compare the efficacy of 2% clindamycin vaginal cream and oral metronidazole for the management of bacterial vaginosis in non-pregnant females.

Study Design: Randomized controlled trial study.

Place and Duration of Study: This study was conducted at the Department of Obstetrics & Gynaecology, M. Islam Teaching Hospital Gujranwala from July 2019 to December 2019.

Materials and Methods: Two hundred cases were enrolled of age 20-40 years presented with clinically proven bacterial vaginosis. Patients were then divided randomly into two groups. Group A were given 2% clindamycin vaginal cream 5gm that was administered vaginally at bedtime for 3 days and group B was given metronidazole capsules 500 mg taken orally twice daily for 7 days and the efficacy was assessed after 1 week.

Results: The mean age in clindamycin group was 31.73 ± 5.77 years and metronidazole group was 29.84 ± 5.88 years. It was found that pH of vaginal fluid become <4.5 in 176 (88%) cases, amine test was negative in 174 (87%) cases and clue cells were absent in 181 (90.5%) cases. Efficacy was achieved in 171 (85.5%) cases, out of which 83 (83%) belonged to clindamycin group and 88 (88%) belonged to metronidazole group. The difference between both study groups was insignificant.

Conclusion: Three day course of clindamycin and 7-day course of metronidazole are equally effective.

Key Words: Bacterial vaginosis, Clindamycin, Metronidazole, Amine test, Clue cells, Vaginal pH

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INTRODUCTION

Bacterial vaginosis (BV) is a common cause of vaginal discharge, and prevalence is 29% in the general population.¹ Bacterial vaginosis is the commonest cause of irregular vaginal discharge in women of childbearing age but may also be present in women with menopause, and is rare in children.² Since these bacteria are difficult to cultivate, their antibiotic resistance is not established.^{3,4}

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It has been related to a large number of obstetrical and gynaecological complications, including preterm labour and delivery; pPROM; chorioamnionitis; endometritis postpartum; infections with post-caesarean injuries and subclinical inflammatory diseases pelvic.^{5,6}

Both clinically and microbiologically, bacterial vaginosis may be diagnosed. For pregnant and non-pregnant women, medical requirements are the same. The clinical diagnosis is made if three of the four indications present as a vaginal adherent and homogenous release, a vaginal pH >4.5 , a detection of clue cells on the mount of saline wet, and potassium hydroxide (positive whiff test) amine odour.⁷

McDonald et al⁸ and Alesna et al⁹ have studied bacterial vaginosis screening and treatment in pregnant women and measured the effectiveness in cure achievement and maintenance of different treatment regimens, including oral and vaginal metronidazole and clindamycin.

In both groups of patients, immediate relief of most of the signs and symptoms was observed about a week after treatment. 15 of 16 (94%) patients were asymptomatic in the clindamycin group and all 17 (100%) in the metronidazole group. Eradication at one month after vaginal clindamycin cream was 66 to 83% compared to 68 to 87% for metronidazole and also

when oral metronidazole and 2% vaginal clindamycin cream were noted with similar effectiveness (85 and 86% respectively) and side effects in contrast with randomized trials.¹⁰⁻¹²

MATERIALS AND METHODS

This randomized controlled trial study was conducted at Department of Obstetrics & Gynaecology, M. Islam Teaching Hospital Gujranwala from 1st July 2019 to 31st December 2019 and 200 cases were enrolled. They were divided in two groups (Group A and Group B), each group comprised 100 cases. Patients were then divided randomly into two groups by using lottery method. Group A were given 2% clindamycin vaginal cream 5gm that was administered vaginally at bedtime for 3 days and patients in group B was given metronidazole capsules 500 mg taken orally twice daily for 7 days. Patients of age 20-40 years presented with clinically proven bacterial vaginosis were included. All pregnant and lactating female, vaginal candidiasis, trichomoniasis, and gonococcal infection associated with BV (assess through clinical and laboratory tests), any systemic problem like DM (BSR>200mg/dl), renal insufficiency (serum creatinine >1.2mg/dl), deranged LFTs (ALT>45IU, AST>45IU) and allergic to metronidazole or clindamycin (assess through history or medical record) were excluded. Efficacy was assessed after 1 week (7 days). All this information was recorded. The data was analyzed through SPSS-20. Chi-square was used to compare the efficacy of both drugs. P-value ≤ 0.05 was considered as significant.

RESULTS

The mean ages of patients were 31.73 \pm 5.77 years in clindamycin group and 29.84 \pm 5.88 years in metronidazole group (Table 1). It was found that pH of vaginal fluid become <4.5 in 176 (88%) cases, amine test was negative in 174 (87%) cases and clue cells were absent in 181 (90.5%) cases (Table 2)

It was found that there were pH of vaginal fluid was <4.5 in 85 (85%) cases in clindamycin group and in 91 (91%) cases in metronidazole group. The difference between both groups was insignificant (P = 0.192). Amine test was negative in 80 (80%) cases in clindamycin group while in 94 (94%) in metronidazole group. The difference between both groups was significant (P = 0.003). Clue cells were absent in 90 (90%) cases in clindamycin group while in 91 (91%) in metronidazole group. The difference between both groups was insignificant (P = 0.809) [Table 3]. Efficacy was achieved in 171 (85.5%) cases, out of which 83 (83%) belonged to clindamycin group and 88 (88%) belonged to metronidazole group. Efficacy could not be achieved in 29 (14.5%) cases, out of which 17 (17%) belonged to clindamycin group and 12 (12%) belonged to metronidazole group. The difference between both

study groups was insignificant (p-value = 0.315) [Table 4].

Table No.1: Descriptive statistics of age (years) of the patients in both groups (n=200)

Variable	Age (years)
Clindamycin	31.73 \pm 5.77
Metronidazole	29.84 \pm 5.88

Table No.2: Frequency of efficacy of the patients with bacterial vaginosis (n=200)

Efficacy of bacterial vaginosis	No.	%
Vaginal fluid pH<4.5	176	88%
Negative amine test	174	87%
Clue Cells absent	181	90.5%

Table No.3: Frequency of efficacy of the patients in both groups (n=200)

Variable	Clindamycin	Metronidazole	P value
Vaginal fluid pH<4.5	85 (85%)	91 (91%)	0.192
Negative amine test	80 (80%)	94 (94%)	0.003
Clue Cells absent	90 (90%)	91 (91%)	0.809

Table No.4: Comparison of efficacy achieved in both groups

Efficacy	Clindamycin	Metronidazole	Total
Yes	83 (83%)	88 (88%)	171 (85.5%)
No	17 (17%)	12 (12%)	29 (14.5%)
Total	100 (100%)	100 (100%)	200 (100%)

Chi-square test = 1.008

P = 0.315

DISCUSSION

The common cause of vaginal excretion, with a prevalence of 29% in the general population, is bacterial vaginosis. Bacterial vaginosis is characterized by a loss of normal, vaginal lactobacilli producing hydrogen peroxide (H₂O₂) and an increase of the presence of anaerobic bacteria. The sequelae of BV can be serious. Pregnant women diagnosed with BV between 8 and 17 weeks of gestation can raise their risk of delivery by up to 7 times before 37 weeks.¹³

We have performed a randomised controlled trial with a mean age of 30.79 \pm 5.89 years and we recruit 200 cases of bacterial vaginosis. The patient's minimum age was 20 years while the patient's median age was 40 years. Both patients were in the category of reproductive age. Literature also quoted the reproductive age group as a concern.¹⁴

The mean age of clindamycin patients was 31.73 \pm 5.77 years, the mean age of metronidazole patients was 29.84 \pm 5.88 years. One study recorded that the mean age of clindamycins received by women was 28 years and the mean age of metronidazole received by women was 29 years.⁹

We found an insignificant difference between the two trial groups in this trial. Treatment efficacy was

achieved in 83 (83%) with 2% vaginal clindamycin and with 88 (88%) oral metronidazole. These findings coincide with other study results. There was no major difference between patients treated with intravaginal clindamycin cream for three days and patients treated with oral metronidazole over seven days.⁹

One investigator compared the normal oral metronidazole method with 2% clindamycin phosphate cream intravaginal. The cure rate for clindamycin did not vary significantly from the oral metronidazole cure rate at 5 to 8 days (72% vs 87% respectively). One month after the end of therapy, 61% of patients remained healed in each group.¹⁵

There were two related studies that were multicentered and included a larger population. Fischbach et al¹⁶ reported a cure or improvement rates of 78% compared to 83% in the clindamycin community, while Luis et al¹⁷ reported the same cure rates of 87% compared to 79%, respectively. These studies did not indicate any important cure difference between normal intravaginal oral metronidazole and 2% clindamycin cream administered over 7 days. Furthermore, both medications have been well tolerated with moderate side effects.

Dhar et al¹⁸ recently conducted a study that assessed the effectiveness and safety of a 2% clindamycin vaginal cream 3-day course in BV therapy. The cure rates for clindamycin for one week were 95.6% and one month after treatment 82.4%, there were three recurrences and no significant adverse effects were reported.

The efficacy of a 3-day intravaginal, 2% clindamycin phosphate cream applied once daily was close to that of regular oral metronidazole in another study (500 mg twice daily for 7 days). The results of this study confirm the findings of Dhar et al¹⁸ previously, and further support the effectiveness and safety of a three day intravaginal, once daily 2% clindamycin phosphate cream in the treatment of BV.

This study showed that pH of vaginal liquid was <4.5 in 85 (85%) cases with clindamycin and 91 (91%) cases with metronidazole (P=0.192), when we compared the two study groups for efficacy parameters. In 80 (80%) of cases of clindamycin the amine test was negative, while in 94 (94%) it was negative with metronidazole (P=0.003). In 90 (90%) cases cluster cells were absent, while 91 (91%) with metronidazole (P=0.809) were absent. Other research have agreed with the findings of our study, and stated that the vaginal photoelectricity in both groups was <4.5 in 80% of clindamycin compared with 87.5% in metronidazole (P=0.93), while all (100%) had negative amine tests and vaginal discharge decreases in both groups.⁹

CONCLUSION

The overall efficacy of treatment was achieved in 171 (85.5%) cases, out of which 83 (83%) belonged to clindamycin group and 88 (88%) belong to

metronidazole group and the difference between both groups was not significant. Thus we can say that 3-day course of clindamycin and 7-day course of metronidazole are equally effective. So we can prescribe 3-day course of clindamycin instead of commonly prescribed 7-day course of metronidazole.

Author's Contribution:

Concept & Design of Study: Samra Ismat
 Drafting: Amna Kazi
 Data Analysis: Pakeeza Aslam
 Revisiting Critically: Samra Ismat, Amna Kazi
 Final Approval of version: Samra Ismat

Conflict of Interest: The study has no conflict of interest to declare by any author.

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