

A Hospital Based Clinical Study Assessing Effectiveness of Clindamycin on Bacterial Vaginosis and Compare with Commonly Used MetronidazoleSuchandra¹, Renu Jha², Kumudini Jha³¹Senior Resident, Department of Obstetrics and Gynecology, Darbhanga Medical College and Hospital, Laheriasarai, Darbhanga, Bihar, India.²Associate Professor, Department of Obstetrics and Gynecology, Darbhanga Medical College and Hospital, Laheriasarai, Darbhanga, Bihar, India³Professor and HOD, Department of Obstetrics and Gynecology, Darbhanga Medical College and Hospital, Laheriasarai, Darbhanga, Bihar, India

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Abstract:**Aim:** The aim of the present study was to assess the effectiveness of Clindamycin on Bacterial Vaginosis and compare with commonly used Metronidazole.**Methods:** A Randomized control study was done at Department of Obstetrics and Gynaecology for one year. Total 100 women were selected in the study.**Results:** The two groups were comparable with respect to symptoms before and after treatment among study participants. Clindamycin was better than metronidazole with respect to Amsel's criteria after treatment ($P < 0.05$). Clindamycin was better than metronidazole with respect to Nugent's criteria after treatment ($P < 0.05$). Clindamycin was better than metronidazole with respect to Culture results after treatment ($P < 0.05$).**Conclusion:** Oral Clindamycin may be preferable to oral Metronidazole because of its broader spectrum of activity. We have proved in our study that Clindamycin is better than Metronidazole but more studies need to be conducted in future. These findings can be used to provide better treatment for the women with Bacterial Vaginosis.**Keywords:** Bacterial vaginosis, White discharge, Metronidazole, Clindamycin.

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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. Common anaerobic pathogens associated with BV are Gardnerella vaginalis, Prevotella species, Mobiluncus species, Mycoplasma hominis, and Atopobium vaginalis. [2] Women in their reproductive age group are most commonly affected by BV and present clinically as abnormal foul-smelling vaginal discharge. [3]

BV has an increased susceptibility to herpes simplex virus infection, human papilloma virus infection, human immunodeficiency virus (HIV), and other sexually transmitted diseases. [4,5] It is associated with serious sequelae such as increased

risk of preterm deliveries, first-trimester miscarriages, chorioamnionitis, postpartum and postabortal endometritis, and pelvic inflammatory disease affecting the quality of life in these women. [6,7] BV treated with nitroimidazoles carries significant positive outcome. Metronidazole, a nitroimidazole antimicrobial agent, has been used in clinical medicine for more than 45 years and currently is the drug of choice for all anaerobic infections. [8] Metronidazole administered either orally or topically according to multiple dose regimen has long been established as a standard treatment of BV, with 77.9% cure rate. [9-11] However, necessity to administer the drug for longer duration potentially reduces compliance, thus increasing the risk of incomplete cure and recurrence of BV. [12]

In 2015 guidelines regarding sexually transmitted disease treatment, the CDC recommended BV treatment with a 7-days regimen of 500 mg of Tab. Metronidazole two times daily, a 5-days regimen of 0.75% Metronidazole gel administered

intravaginally [13] and a 7-days regimen of 2% Clindamycin cream administered intra vaginally was used. Metronidazole provides excellent action against obligate anaerobes but is not effective against aerobes and facultative anaerobes, while Clindamycin has broader spectrum of activity against the gram-positive aerobes and anaerobes. [14]

The aim of the present study was to assess the effectiveness of Clindamycin on Bacterial Vaginosis and compare with commonly used Metronidazole.

Materials and Methods

A Randomized control study was done at department of obstetrics and Gynaecology, Darbhanga Medical College and Hospital, Laheriasarai, Darbhanga, Bihar, India for one year. Total 100 women were selected in the study.

All study subjects were examined in the OPD. Under aseptic precautions a High vaginal swab was taken and sent to microbiology lab for culture and sensitivity and using Amsel's criteria and Nugent's criteria diagnosis was noted.

Amsel's composite criteria include: [15,16]

1. If pH of vagina is > 4.5
2. If clue cells are present in gram-stained vaginal discharge smears and
3. If whiff test is positive.
4. Characteristic Vaginal discharge.
5. According to Amsel's, if 3 of the 4 criteria

are positive, the patient is diagnosed as Bacterial Vaginosis.

Nugent's criteria [15,16]

It evaluates three types of bacteria by Gram staining: Lactobacillus, Bacteroides and Mobilincus. The study population is divided into 2 groups randomly Group-M Group-C, 50 each by computer generated list of random numbers using simple randomization technique. Patients were blinded to the study drug, treated and monitored by the Gynaecologists who were aware of the drug.

Informed consent was taken stating their commitment to take the drugs as given. Group 'M'(Metronidazole) will be given Tab. Metronidazole 400mg TDS for seven days, while Group 'C' (Clindamycin) were given TAB.Clindamycin 300mg twice daily for seven days. The study subjects were followed up after two weeks of completion of treatment. Then, a vaginal swab is taken again for laboratory test, using Amsel's criteria and Nugent's criteria, those who turned negative were noted. Those who remained positive are recorded as the treatment failures and further management is done accordingly.

Statistics and analysis of data

Data was entered in MS-EXCEL and statistical analysis was done by SPSS 24 software. These results were presented in descriptive statistics and appropriate test of significance were applied with 5% level of significance and 95% confidence interval.

Results

Table 1: Symptoms before treatment among study participants

| | Metronidazole | Clindamycin | P value |
|-------------------------|---------------|-------------|---------|
| Symptoms Itching | | | |
| Yes | 34 | 32 | 0.86 |
| No | 16 | 18 | |
| LBA | | | |
| Yes | 18 | 15 | 0.89 |
| No | 32 | 35 | |
| Abdominal pain | | | |
| Yes | 20 | 18 | 0.85 |
| No | 30 | 32 | |
| Fever | | | |
| Yes | 5 | 4 | 0.72 |
| No | 45 | 46 | |

The two groups were comparable with respect to symptoms before treatment among study participants.

Table 2: Symptoms after treatment among study participants

| Symptoms | Metronidazole | Clindamycin | P value |
|----------------|---------------|-------------|---------|
| Itching | | | |
| Yes | 16 | 18 | 0.75 |
| No | 34 | 32 | |
| LBA | | | |
| Yes | 5 | 3 | 0.61 |

| | | | |
|-----------------------|----|----|------|
| No | 45 | 47 | |
| Abdominal pain | | | |
| Yes | 11 | 10 | 0.65 |
| No | 39 | 40 | |
| Fever | | | |
| Yes | 4 | 4 | 0.54 |
| No | 46 | 46 | |

The two groups were comparable with respect to symptoms after treatment among study participants.

Table 3: Amsel's criteria after treatment

| Criteria | Metronidazole | Clindamycin | P value |
|----------|---------------|-------------|---------|
| Positive | 12 | 6 | |
| Negative | 38 | 44 | 0.03 |
| Total | 50 | 50 | |

Clindamycin was better than metronidazole with respect to Amsel's criteria after treatment ($P < 0.05$).

Table 4: Nugent's criteria after treatment

| Criteria | Metronidazole | Clindamycin | P value |
|----------|---------------|-------------|---------|
| Positive | 10 | 4 | |
| Negative | 40 | 46 | 0.01 |
| Total | 50 | 50 | |

Clindamycin was better than metronidazole with respect to Nugent's criteria after treatment ($P < 0.05$).

Table 5: Culture results among study participants

| Culture | Metronidazole | Clindamycin | P value |
|---------|---------------|-------------|---------|
| Sterile | 38 | 45 | |
| Growth | 12 | 5 | 0.03 |
| Total | 50 | 50 | |

Clindamycin was better than metronidazole with respect to Culture results after treatment ($P < 0.05$).

Discussion

BV is a common disorder, yet poorly understood poly-microbial vaginal infection. It is more commonly seen in women in reproductive age group. It has high prevalence in African women especially those in sub-Saharan Africa. [17] Approximately 50-69% of women with BV are not symptomatic and women who presents with symptoms varies from Gray-white offensive vaginal discharge intensified after sexual intercourse and during menstruation, lower abdominal pain and dyspareunia. BV is diagnosed by two different criteria such as Amsel's and Nugent's. [18] After the diagnosis according to the above criteria, CDC & ACOG recommended either orally or Intravaginally Metronidazole or Clindamycin is given to treat BV. [19]

The two groups were comparable with respect to symptoms before and after treatment among study participants. Clindamycin was better than metronidazole with respect to Amsel's criteria after treatment ($P < 0.05$). Clindamycin was better than metronidazole with respect to Nugent's criteria after treatment ($P < 0.05$). Clindamycin was better than metronidazole with respect to Culture results after treatment ($P < 0.05$). Clinical trials comparing two different antimicrobial treatments found they were clinically equivalent, [20] approving 50%

recurrence rates after six months. [21] Clindamycin has greater anti-gram-positive anaerobe and aerobic spectrum action, while Metronidazole is more effective against obligate anaerobes but less effective against aerobes and facultative. [22]

A study similar to our study was done by D G Ferris et al. one week of oral Metronidazole 500 mg twice daily, five days of 0.75% Metronidazole vaginal gel, or seven days of 2% Clindamycin vaginal cream, were given to 100 women who had been diagnosed with bacterial vaginosis using conventional criteria. [23-25] Women who also had vaginal trichomoniasis or vulvo-vaginal candidiasis were not included. For the treatment of bacterial vaginosis, oral metronidazole, metronidazole vaginal gel, and clindamycin vaginal cream all had approximately identical cure rates. [26] Similar rates of post-treatment vulvo-vaginal candidiasis were observed in patients treated with these treatments, although those utilising the intra vaginal products expressed greater satisfaction with the course of treatment. [27-29]

Metronidazole is active against anaerobes, whereas clindamycin has broader spectrum activity against Gram-positive aerobes and anaerobes. The microbial flora pattern following treatment with clindamycin differs to metronidazole, with greater reduction in *Mobiluncus* spp and higher frequency of clindamycin-resistant anaerobes. [30-32] Meltzer also confirmed the relative resistance of *Mobiluncus* spp to metronidazole therapy, and

showed their persistence was associated with increased risk of BV recurrence. [33] Based on these data and the polymicrobial nature of BV, one might postulate that higher cure rates could be reached by combining metronidazole and clindamycin. Researchers Hantoushzadeh et al [34] (96.20%) found the highest clinical cure rates for BV treatments similar to our study among women while examining who are pregnant and not pregnant women, respectively. One group of 250 pregnant women in Iran was given the probiotic treatment of eating mixed-lactobacilli yoghurt, while the other group was given the antibiotic treatment of eating Clindamycin orally (300 mg). In our study comparing with the prevalence of bacterial vaginosis (BV) was found to be 23% in the study by Ieoma et al [35] which is consistent with other local investigations that found bacterial vaginosis prevalence among pregnant women to range from 17.3% to 64.3%. There are pronounced differences in prevalence between nations, races, and even groups living in the same nation.

Conclusion

Oral Clindamycin may be preferable to oral Metronidazole because of its broader spectrum of activity. We have proved in our study that Clindamycin is better than Metronidazole but more studies need to be conducted in future. These findings can be used to provide better treatment for the women with Bacterial Vaginosis. The risk of bacterial vaginosis increases with multiple sexual partners and poor hygiene, adolescent girls and young women should be appropriately educated about avoidance of multiple sexual partners, use of barrier contraception and maintenance of proper personal hygiene.

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