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### STUDY OF CLINICO-EPIDEMIOLOGY AND MANAGEMENT PRACTICES OF BACTERIAL VAGINOSIS

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#### ABSTRACT

**BACKGROUND:** Bacterial vaginosis is an infection in the vaginal region caused due to shift in microflora. Untreated vaginosis can often lead to severe complications such as pelvic inflammatory disease, cervicitis, salpingitis, endometritis, infertility, ectopic pregnancy and preterm delivery. This study therefore, aimed to determine clinico-epidemiology and management practices of Bacterial vaginosis. **METHODS AND METHODOLOGY:** For 117 women attending OP of OBGY, samples were collected and subjected for pH test, whiff's test. Smear was prepared and subjected for gram's staining for clue cell determination and nugent scoring. They were treated according to the guidelines and counselled for personal hygiene. The patients are asked for follow up after 4 weeks to evaluate therapeutic outcomes. **RESULTS:** Out of 117 women tested for BV, 24 were positive. It shows the prevalence of 20.5%. Amongst them 21% were found to be asymptomatic. Prevalence of BV in non-pregnant women was 25.4% and none of the pregnant women were tested positive. Prevalence rate was high (28%) between the age group of 30-39 years. Vaginal discharge is common in both positive and negative patients. Clue cells test and gram staining was found to be more appropriate for diagnosis of BV. Treatment with metronidazole and clindamycin have shown positive outcome. **CONCLUSION:** The prevalence of Bacterial vaginosis was found to be low in our study. BV was found to be prevalent even in asymptomatic. Since method of identification was simple, cost effective and less time consuming all patients with vaginal discharge can be screened for early identification of disease and prevention of its complications.

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## INTRODUCTION

Bacterial vaginosis is a polymicrobial infection in the vagina caused due to shift in microflora. It is characterized by an increase in the vaginal pH which makes the vaginal area basic which occurs by reduction in lactobacilli predominantly lactic acid and H<sub>2</sub>O<sub>2</sub> producing species and an increase in facultative and anaerobic bacteria such as Gardnerella vaginalis, Prevotella, Atopobium, Mobiluncusetc.<sup>(1)</sup>

The prevalence of Bacterial Vaginosis differs widely from country to country and within the same region. The prevalence of bacterial vaginosis is 29.2% worldwide. BV is more frequent in black females, as compared to white females independent geographical distribution. Although younger women of age 14 to 19 years had a somewhat lower prevalence (23.3%) of bacterial vaginosis. Among the 20 years and older group the prevalence was between 28% to 31%.<sup>(2)</sup>

The prevalence of bacterial vaginosis varied significantly with race, education and poverty ratio.<sup>(3)</sup> the prevalence of BV among pregnant women with abnormal vaginal discharge was 17.3%. Age 20-24 years, multigravidity, lack of western education and un-employment were associated with increased prevalence of BV.<sup>(4)</sup>

Clinical features seen in bacterial vaginosis are due to increased exfoliation of squamous epithelial cells. Normal symptoms include the following: Water, thin, Grey or white in colour vaginal discharge, strong and unpleasant smell, often described as fishy odour, Less commonly burning sensation during micturition., Itching around outside vagina., Pruritis, lower abdominal pain and pain during coitus. In normal women 50-75% of patients are asymptomatic. it is in pregnant women 15.9%.<sup>(5)</sup> Risk factors include bathing with antiseptic liquids, multiple sex partners, rise in vaginal pH due to estrogen depletion, douching, usage of vaginal deodorants & scented soaps and using IUD's.<sup>(6)</sup> Complications include HIV, STI, postsurgical infections around vagina, PID, tubal factory infertility<sup>(7)</sup> and some gynecological complications like cervicitis, salpingitis, endometritis, oophoritis. At times, it may lead to ectopic pregnancy or loss of pregnancy too.

## DIAGNOSIS

### Whiff test (amine odor test):

Adding few drops of 10% potassium hydroxide to a sample of vaginal discharge. A strong fishy odour indicates positive result of the test.

### pH test:

The pH of vaginal discharge can be obtained by placing the sample on pH paper. The pH paper turns its colour. Blue litmus paper turns to red indicates positive test.

### Gram staining:

Nugent score is a gram stain scoring system for vaginal swabs to diagnose bacterial vaginosis. The Nugent score is calculated by assessing the presence of large gram positive rods (lactobacillus morphotypes; decrease in lactobacillus scored as 0 to 4), and curved Gram-variable rods (Mobiluncus morphotypes; scored as 0 to 2). A score of 7-10 is consistent with bacterial vaginosis without culture.

A score of 0-10 is generated from combining three other scores. The scores are as follows:

0-3 is considered negative for BV.

4-6 is considered intermediate for bacterial vaginosis.

7+ is considered indicative of BV.<sup>(8,9)</sup>

### Amsel criteria:

- Thin, white, yellow homogeneous discharge.
- Clue cells on microscopy.
- pH of vaginal fluid >4.5.
- Release of a fishy odour on adding 10% KOH drops.

At least three of four criteria should be present for a confirmed diagnosis.<sup>(10)</sup>

A modification of the Amsel criteria accepts the presence of two instead of three factors and is considered equally diagnostic as per the study conducted by Gutman, Robert et al.<sup>(11)</sup>

## Treatment

### Recommended regimens based on CDC guidelines:

**Metronidazole Tablets:** metronidazole 500mg taken orally twice daily for 7 days. it is the most effective and preferred treatment. A single tablet: taken orally as a one time dose. Recurrence of BV is more with this treatment. **Gel:** 0.75%, one full applicator (5 gm) intra-vaginally, once a day for 5 days.

**Clindamycin:** It is an alternative antibiotic available in different forms. Clindamycin cream 2%, one full applicator (5g) intra-vaginally at bedtime for 7 days.<sup>(12)</sup>

**Tinidazole:** It is another antibiotic which may be sometimes used to treat BV if metronidazole doesn't work taken by mouth as single dose. Tinidazole has a better pharmacokinetic and longer half-life than metronidazole and is recommended for the treatment of BV.<sup>(13)</sup>

**Probiotics:** Antibiotics can breakdown the overgrowth of vaginal anaerobes and formation of biofilm. Consequently, probiotics administered intra-vaginally will adhere to vaginal wall and colonize epithelial cell surfaces.<sup>(14)</sup>

**Patient counselling points:**

Vaginal douching (pushing water into vagina) to be avoided as vagina doesn't require specific cleaning. Strong detergents for underwear to be avoided. Sex partners to be limited. Moist environment always encourages the risk of infections. So, always vaginal area to be maintained dry. Tight nylon pants and thongs to be avoided. Always prefer condoms to prevent transmissible infections. Sexual participation during infections to be predominantly avoided. Sanitary pads should be changed every 6-8hrs during periods. Consulting doctor is advisable in the case of heavy periods. Don't stop the medication even if symptoms resolved complete total course as prescribed.<sup>(15)</sup>

**MATERIALS AND METHODS**

Over a period of 6 months 117 patients were observed. Inclusion criteria included patients in between age group 18-45years, both pregnant and non-pregnant, with both normal and abnormal discharge, no antibacterial therapy with in three weeks prior to their attendance. Patients who are willing for study follow up. Patients with genital malignancy and who are not willing to participate in the study were excluded. After explaining the purpose of the study, written informed consent were obtained from patient..A detailed medical history, family history, menstrual history including the irregularities will be noted. During the clinical examination, a direct smear was prepared by transferring vaginal fluid on to a glass microscopic slide with a cotton-tipped applicator stick. The slides were alcohol fixed, stained and air dried labelled with the date of collection and the patient's study number and stored in the dark.

**The sample was subjected to following tests:****pH test :**

Vaginal sample was placed on a red litmus paper. If the red litmus turns blue, it is considered positive.

**Whiff test:**

Place a drop of vaginal discharge on a slide and add drop or 2 of 10% potassium hydroxide (KOH). Characteristic fishy odour (foul smell) indicates positive test.

In the laboratory, the smears will be alcohol fixed and stained by the Gram stain and using saffranin as the counterstain.

**Identification of clue cells:**

Clue cells are vaginal epithelial cells stained by crystal violet dye. They show distinctive stippled appearance as they are flodded and being eaten by bacteria.<sup>(16)</sup>

Presence of clue cells on the stained smear is one of the major determining criteria for determining bacterial vaginosis.

**Nugent scoring by gram staining:**

Score 7-10 is considered positive for bacterial vaginosis

**RESULTS AND DISCUSSION**

Out of 106 non-pregnant samples, 24 were tested positive for bacterial vaginosis. This constitutes the prevalence of bacterial vaginosis among non-pregnant women was found to be 25.44%.

In our study we haven't found any bacterial vaginosis positive patients among pregnant women as shown in figure 1. In our study among all the positive samples it was observed that, maximum prevalence of bacterial vaginosis was found in women within the age group of 30-39 years as shown in figure 2. In our study we have found that 21% of BACTERIAL VAGINOSIS POSITIVE SUBJECTS are ASYMPTOMATIC as shown in figure 3.

In our study it is observed that, 79.1% of Bacterial vaginosis subjects were found to have Abnormal vaginal discharge as the main symptom. Itching was found in about 33% of women with bacterial vaginosis. Foul smell was found in about 37.9% of women with bacterial vaginosis. Abdominal pain was found in about 41.6% of women with bacterial vaginosis as shown in figure 4. It was found in our study that, clue cells and gram staining has highest sensitivity and specificity as shown in figure 5.

Table 1 shows that In our study it was observed that, pH >4.5 was found in 95.8% of women with bacterial vaginosis and pH >4.5 was found in 25.8% of women without bacterial vaginosis.

In our study, it was observed that, Whiff test was found positive in 70.8% of women with bacterial vaginosis and Whiff test was found positive in 21.5% of women without bacterial vaginosis as shown in table 2.

In our study it was observed that, Abnormal vaginal discharge was found in 82.6% of women with bacterial vaginosis. Abnormal vaginal discharge was found in 48.3% of women without bacterial vaginosis as shown in table 3. In our study it was found that, Clue cells were found in every (100%) women with bacterial vaginosis and Clue cells were not found in any women without bacterial vaginosis as shown in table 4. In our study 79% of the patients were treated with metronidazole and 21% of them were treated with clindamycin as shown in figure 7. Post treatment during follow up, the patients underwent regular physical examination and their samples were collected again. These samples were subjected for all the tests again. Among 24 patients, 21 were recovered and sown no further symptoms. 3 women remained unrecovered and they are subjected for further gynecological evaluation as shown in figure 8.

24 patients were tested positive by gram staining and amsels criteria. Out of them 19 patients were treated with Metronidazole (500mg, orally, twice a day for 7 days) and other 5 were given Clindamycin cream 2% (1 full applicator, intravaginally, bed time for 7 days). These patients were specially counselled on menstrual and personal hygiene and advised for followup after 4 weeks.

During follow up patients underwent personal check up from the physician, swab was collected from the patients and subjected for tests (pH , whiff test, clue cells and nugent scoring).

Out of 24 patients tested for follow up, 21 patients were recovered. The symptoms were resolved and tests were negative. 3 patients were not recovered, showed the symptoms and tests were positive.

Those unresolved patients were subjected for further gynaecological evaluation. Out of 117 samples screened for the presence of bacterial vaginosis, 24 samples were tested positive. This constitutes the prevalence of bacterial vaginosis was 20.5% in overall sample size.

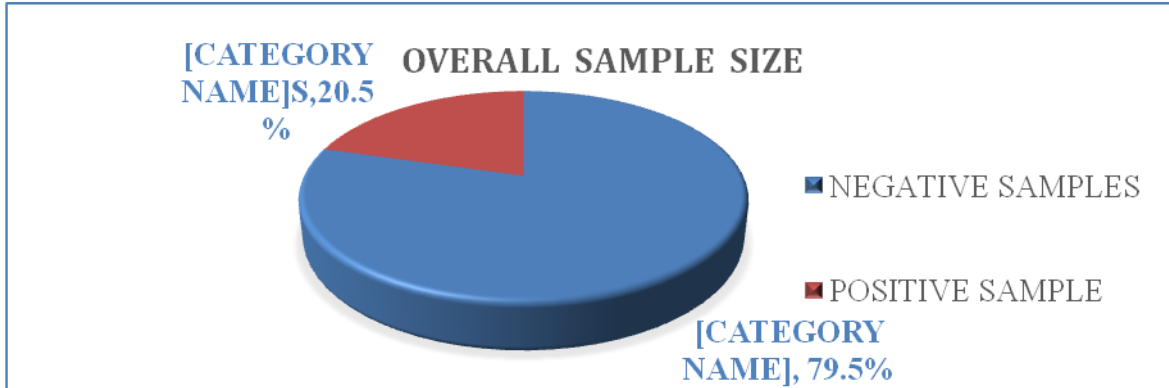


Figure 1: Illustrates prevalence of bacterial vaginosis in overall sample size.

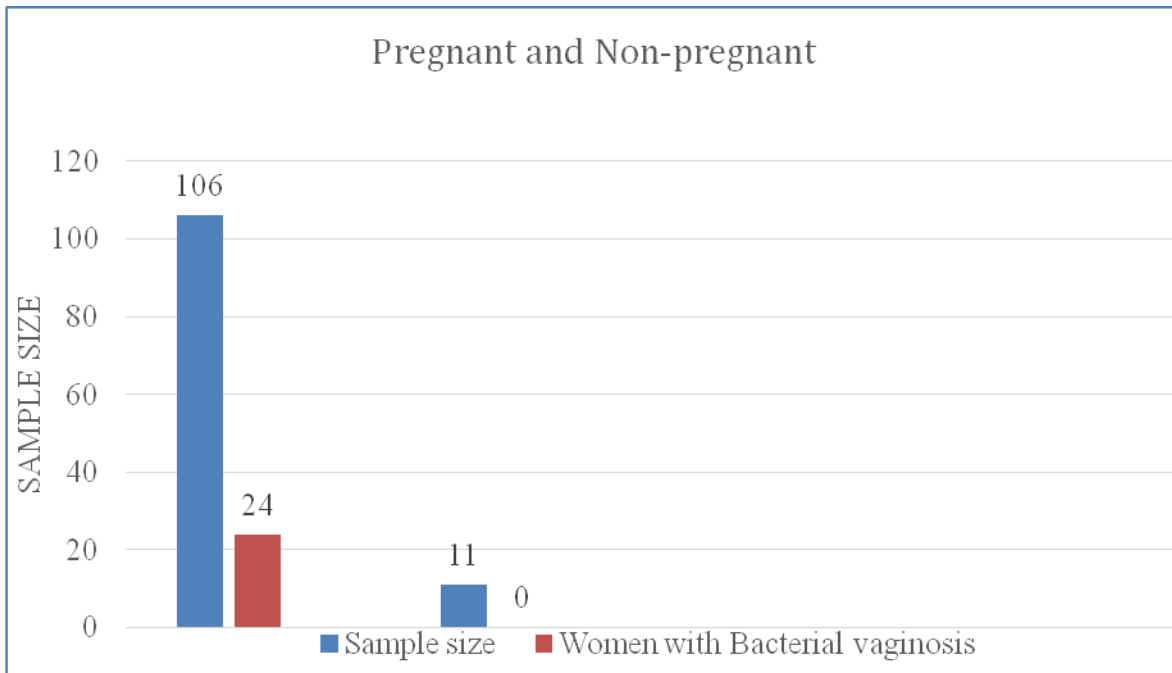


Figure2: Illustrates prevalence of bacterial vaginosis in pregnant and non-pregnant.

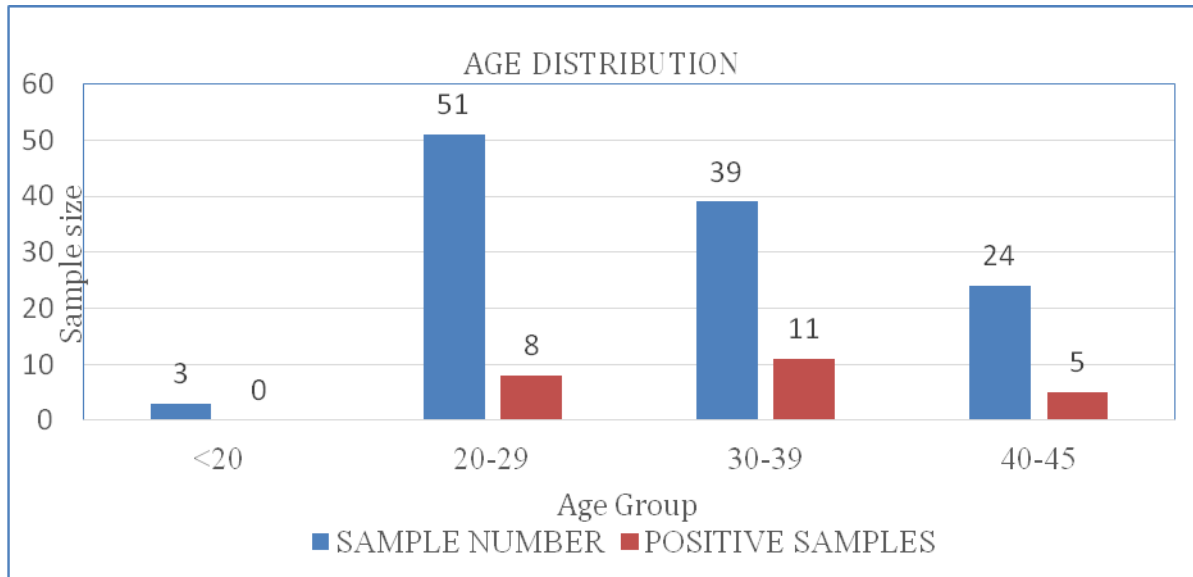


Figure3: Illustrates prevalence of bacterial vaginosis distributed according to age group.

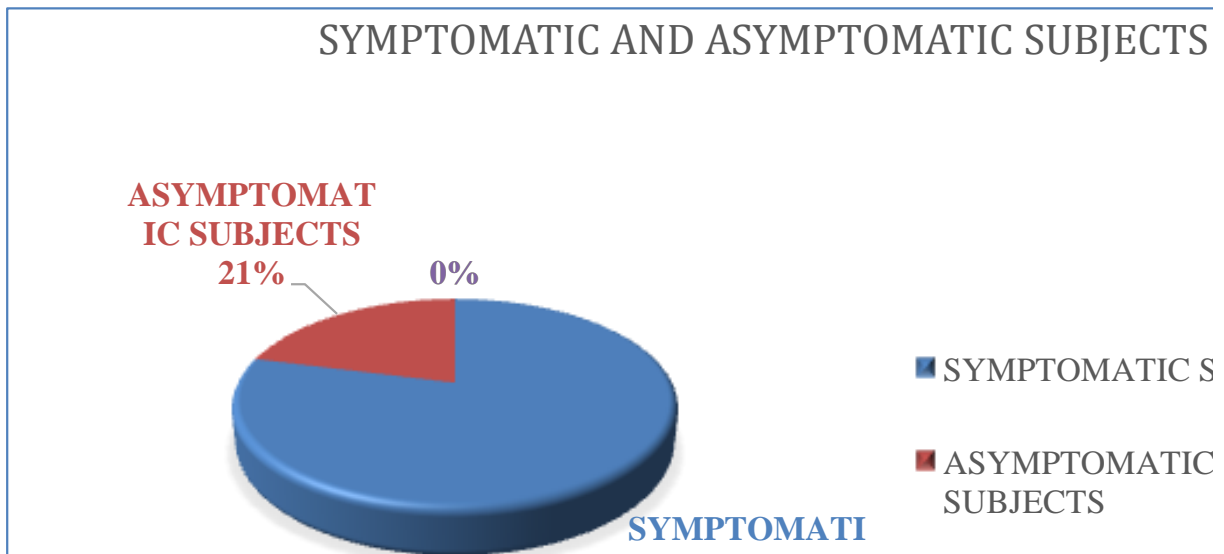


Figure 4: Illustrates prevalence of bacterial vaginosis in symptomatic and asymptomatic subjects.

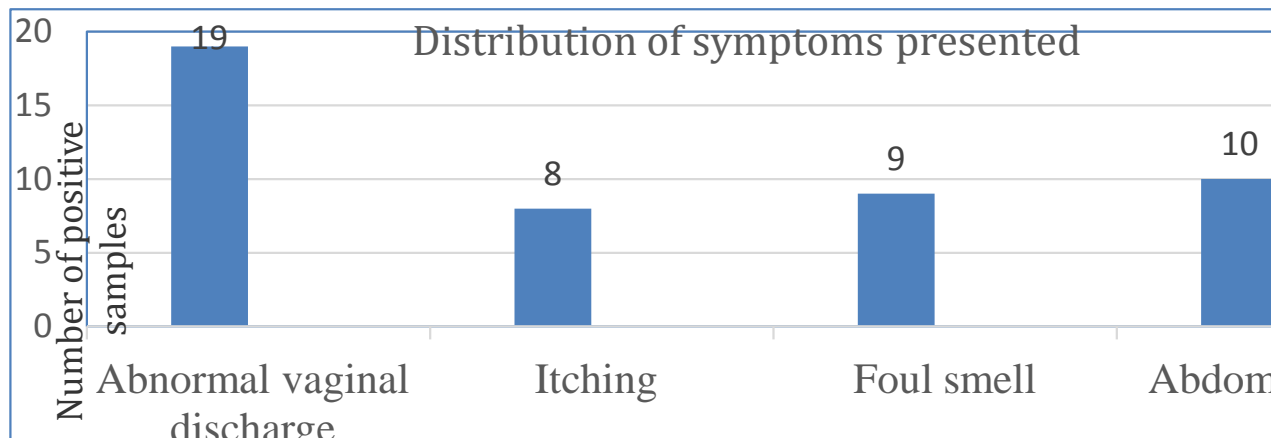


Figure 5: Illustrates frequency distribution of symptoms presented bacterial vaginosis.

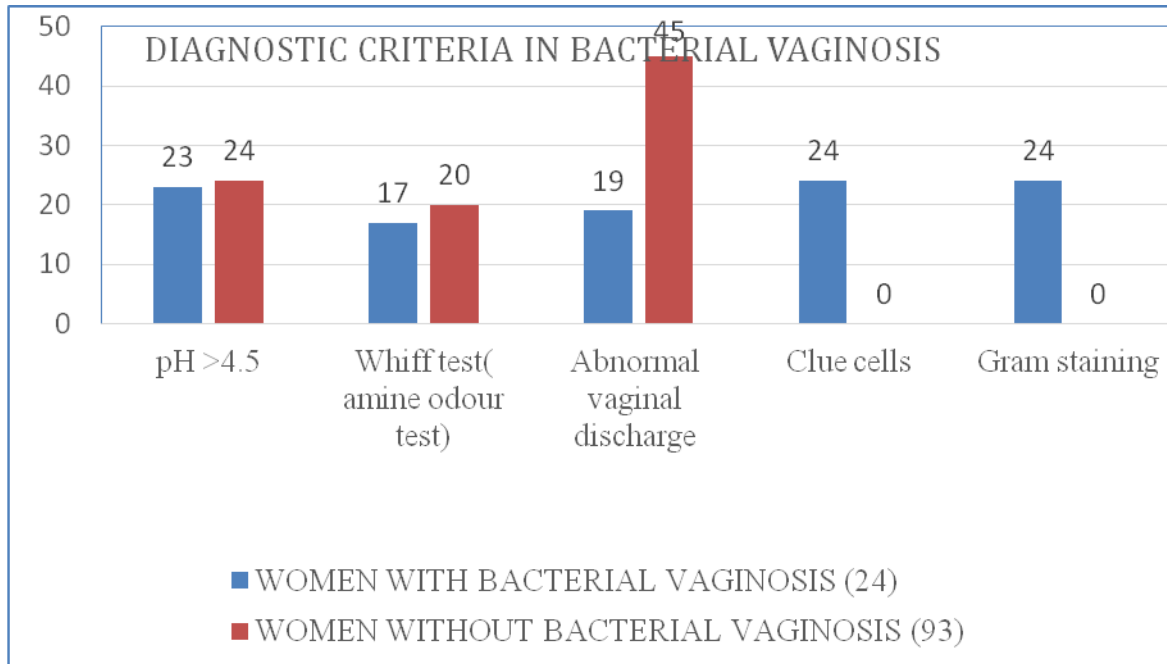


Figure 6: Illustrates frequency distribution of diagnostic criteria in bacterial vaginosis.

Table 1: Diagnostic Accuracy of Ph Test for Diagnosis of Bacterial Vaginosis

VARIABLE	pH >4.5	Percentage
Women with bacterial vaginosis (24)	23	95.8%
Women without bacterial vaginosis (93)	24	25.8%

Table 2: Diagnostic accuracy of whiff test for diagnosis of bacterial vaginosis.

Variable	Whiff test (amine odour test)	percentage
Women with bacterial vaginosis (24)	17	70.8%
Women without bacterial vaginosis (93)	20	21.5%

Table 3: Diagnostic accuracy of abnormal vaginal discharge for diagnosis of bacterial vaginosis.

Variable	Abnormal vaginal discharge	percentage
Women with bacterial vaginosis (24)	19	82.6%
Women without bacterial vaginosis (93)	45	48.3%

Table 4: Diagnostic accuracy of presence of clue cells for diagnosis of bacterial vaginosis.

Variable	Clue cells	percentage
Women with bacterial vaginosis (24)	24	100%
Women without bacterial vaginosis (93)	0	0%

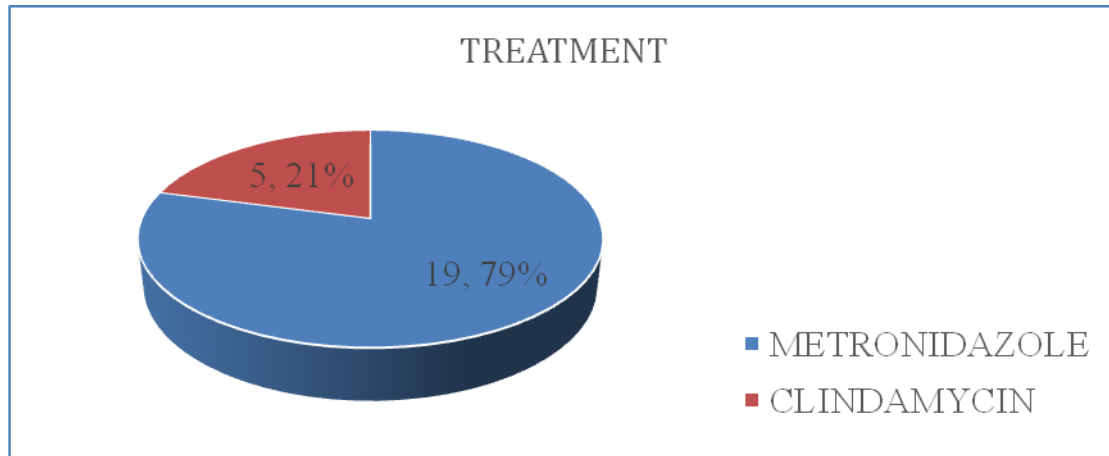


Figure 7.: Illustrates Treatment given to patients diagnosed with bacterial vaginosis.

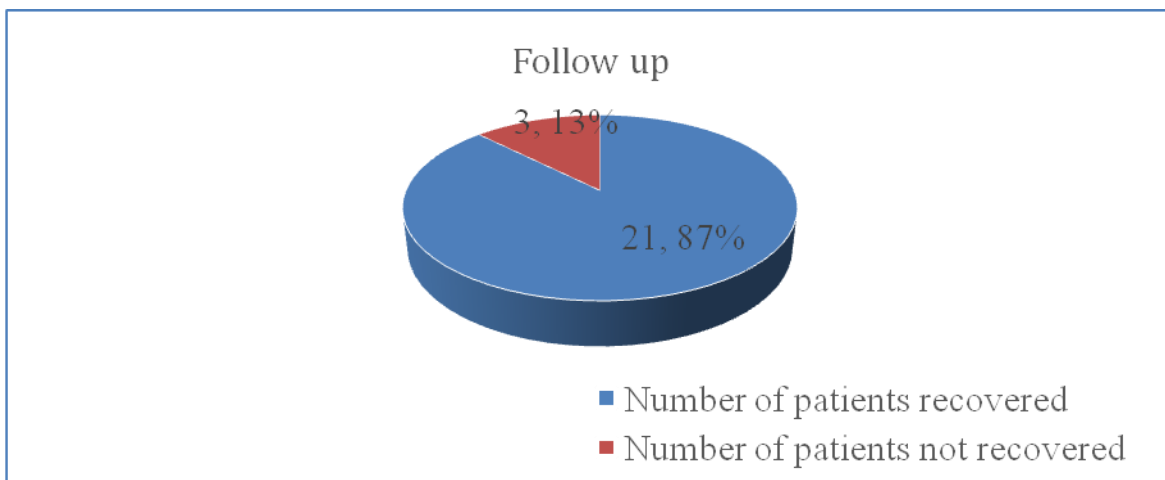


Figure 8.: Illustrates follow up in bacterial vaginosis.

## DISCUSSION

In a study conducted by Gupta Geeta at Ghaziabad, they included 400 sexually active married women. They had found that the prevalence of bacterial vaginosis to be 47.75%,<sup>(17)</sup> Where in our study 117 samples were screened (including both pregnant & non-pregnant) for bacterial vaginosis). The prevalence of bacterial vaginosis was found to be 20.5%. The highest prevalence of bacterial vaginosis (28%) was in between the age group of 30-39 years.

Previous study by P.Balla had shown high percentage of asymptomatic (31.2%) subjects had bacterial vaginosis,<sup>(18)</sup> In our study we found 21% of bacterial vaginosis positive subjects were asymptomatic. Since most of the positive patients were asymptomatic and they are less likely to seek treatment they will be at risk to acquire other sexually transmitted infections. So, asymptomatic women should also be screened and treated for bacterial vaginosis .

Our study has found that in women with bacterial vaginosis 19 out of 24 had abnormal vaginal discharge and in women without bacterial vaginosis 45 out of 93 had abnormal discharge as symptom. It shows the symptom vaginal discharge didn't differ between bacterial vaginosis positive and negative patients. Other symptoms like foul smell/odour , itching and abdominal pain were less frequent. Abnormal vaginal discharge was reported to be more severe in subjects with bacterial vaginosis. These results are similar with a previous study conducted by Klebenoff, Mark et al.<sup>(19)</sup>

Farnaz Mohammadzadeh study has compared various diagnostic methods of bacterial vaginosis and indicated the prevalence of clue cells as the individual Amsel's criteria with highest specificity and sensitivity and concluded that in absence of gram staining, Amsel's criteria can be used as a practical method for diagnosis of bacterial vaginosis.<sup>(20)</sup>

In our study all the bacterial vaginosis positive subjects shown the presence of clue cells and none of the negative subjects had them in the vaginal smear. This shows identification of clue cells has highest sensitivity and specificity and all the bacterial vaginosis positive subjects in our study has satisfied the rule of amsel's criteria (3 out of 4) along with Nugent scoring: 7-10.

## CONCLUSION

The prevalence of bacterial vaginosis was found to be low in our study. Among positive patients prevalence of bacterial vaginosis was found more in between the age group 30-39 years. Bacterial vaginosis was found to be prevalent even in asymptomatic subjects. So all the patients with both normal and abnormal discharge should be screened for the presence of bacterial vaginosis. Bacterial vaginosis was found to be more prevalent in non-pregnant women than pregnant women. There was no prevalence found in pregnant women in our study. But this can't be given as a final conclusion. As the sample size is very low the sample size to be extended for deriving the final conclusion in further study. Metronidazole and clindamycin had shown effective treatment. Proper patient counselling, menstrual hygiene had supported the therapeutic outcome. The method of identification is very simple, easy, less time consuming and cost effective. With this knowledge we can suggest medical fraternity to screen all women with the complaint of vaginal discharge for the presence of bacterial vaginosis. It had shown that proper hygiene practices along with therapeutic management had a remarkable effect on improving quality of life of the patient.

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## Conflicts of Interest

No conflicts of interest have been declared.

## Informed Consent

Informed consent was obtained from all individual participants included in the study.

## Ethics Approval

All procedures performed in studies involving human participants were in accordance with the ethical Standards of the Institutional Ethics Committee and with the 1964 Helsinki declaration and its later amendments or Comparable ethical standards.

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