#### **ORIGINAL ARTICLE**

# Frequency of Bacterial Vaginosis and its Fetomaternal Consequences: A prospective study

SHAZA KHAN¹, MUHAMMAD ASIM IQBAL², AYESHA MUNIR³, PARI IMAM GUL⁴, ASMA MUMTAZ⁵, MIAN ADNAN ASLAM® <sup>1</sup>Senior Registrar <sup>2</sup>Assistant Professor <sup>3,4,5</sup>MO <sup>6</sup>Statistical Analyst Department of OBS & Gynecology, NMU & H Multan, BAT Multan

Correspondence to Dr Muhammad Asim Igbal, Email: drasim1211@gmail.com

#### **ABSTRACT**

Aim: To evaluate the incidence rate of bacterial vaginosis in pregnant women and to ascertain its obstetric consequences. Study design: A prospective, cohort study

Place & duration of study: From 3rd June 2020 to 3rd June 2021 in the gynecology department of Nishtar Medical Hospital. Methodology: A total of 250 pregnant women who have surpassed their 10 weeks of gestation were included in the study.

Vaginal swab samples were collected and microbiological testing was performed. Nugent scores and Amsel's composite criteria were used for diagnosing bacterial vaginosis and classifying women into bacterial vaginosis, non-bacterial vaginosis, and intermediate bacterial vaginosis. A mid-sample urine sample was also cultured to diagnose urinary tract infection in analyzed women. All women were then followed-up during the remaining pregnancy course for adverse antenatal events and newborn conditions were also observed.

Results: Out of the total of 250 women, 19.2% were diagnosed positive for bacterial vaginosis. Candidiasis was the secondlargest reported infection among the analyzed women affecting 4.8% of women. Bacterial vaginosis was significantly higher in women aged between 18-25 years, in nulliparous women, and those in lower social class (p<0.05). Abortion (6.25%), preterm labor (43.7%), premature rupture of membranes (PROM) (27%), and puerperal pyrexia (4.1%) were the most considerable adverse outcomes and were significantly higher in the bacterial vaginosis group.

Conclusion: Bacterial vaginosis is significantly higher in pregnant women and is associated with adverse pregnancy outcomes such as abortion, preterm labor, puerperal pyrexia, and premature rupture of membranes.

Keywords: Bacterial vaginosis, vaginal infections, pregnant women, urinary tract infection, fetomaternal outcomes

## INTRODUCTION

Bacterial vaginosis (BV), a highly prevalent vaginal disorder, is recognized as a one of the major causes of vaginitis in both nonpregnant and pregnant women<sup>1</sup>. Even though it is not considered to be a reportable disease, latest research has found that about 15-30% of non-pregnant women have BV while the occurrence rate is as high as BV among pregnant women<sup>2</sup>. However, since majority of cases are asymptomatic, they remain unreported and thus not treated<sup>3,4</sup>. There are multiple risk factors that lead to BV but smoking, same gender sexual intercourse, multiple sexual partners, intercourse at an early age and intrauterine devices are assumed to be the most common causes of BV.

Earlier assumed to be a benign condition, BV is now linked with many gynecological complications such as spontaneous abortions, pre-labor membranes rupture, preterm labor, preterm delivery, amniotic fluid infection, endometritis, post-hysterectomy vaginal-cuff cellulitis, and pelvic inflammation. The pre-term delivery as a result of BV increases the risk of perinetal mortality up to 70%. These findings suggest that early screening of women for BV and treating it might prevent many complications<sup>5,6</sup>.

To date, to the best of our knowledge, only a few studies have been conducted on pregnant women of Pakistan to ascertain the incidence and intensity of BV. Moreover, the literature has found to be scarce in terms of association between vaginal colonization and adverse maternal and fetal outcome7. Therefore, there is an urgent need to conduct clinical trials to ascertain the frequency of BV among pregnant women in Pakistan and its effect on maternal and fetal outcomes7.

This study aims to determine the frequency of incidence of BV in pregnant women and to ascertain its obstetric consequences. The result of this study will not only create awareness among the masses but will also develop insight in clinicians in preventing BVassociated obstetric complications. The study would assist clinicians to mitigate the incidence of preterm births and other

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obstetric complications by conducting early screening for BV and early treatment of positive cases.

#### **METHODOLOGY**

A prospective, cohort study at Gynecology Department of Nishtar Medical Hospital for 1 year from 3rd June 2020 to 3rd June 2021. A total of 250 women who visited the department after their 10 weeks of gestation were included in the study through a non-probability consecutive sampling technique. The sample size was computed through an online sample size calculator at an 80% value of power set and level of significance less than 0.05. Women with a previous history of BV, any prior experience of obstetric complication, or any comorbidity was excluded from the study. All women were informed of study objectives and signed consent was obtained. Similarly, ethical permission was taken from the ethical committee of the hospital. All the included women were inquired of their social, sexual, obstetrical, and medical history through a self-administered questionnaire. The women were evaluated for the presence of pathogenic organisms in the vaginal area and the nature of the vaginal discharge. A sterilized and unlubricated speculum was passed into the vagina for sample collection The collected discharge then underwent Whiff testing to check for "Fishy odor". Two swabs samples were collected. One among them was used for estimating pH and gram staining of collected material while the other swab was used for culture studies. To assess UTI, midstream urine was collected in a clean container and the sample was cultured on suitable media for analysis9. The detection of microorganisms was made according to the already described method<sup>20</sup>. Microscopic examination of gram stained slides was done and women were characterized as BV, intermediate Bacterial vaginosis, or non-bacterial vaginosis according to criteria suggested by Nugent et al10 BV was further confirmed by using Amsel's composite criteria<sup>11</sup> under which women were positive for 3 of the following criteria classify for BV: 1) vaginal pH >4.5; 2) positive Whiff test; 3) finding of clue cell on unstained slides, and 4) homogenous vaginal discharge. The women who tested positive for BV were administered oral clindamycin 300 mg for a week. All women were then examined by their consultant gynecologists on

every antenatal visit throughout their course of pregnancy for assessment of adverse obstetric outcomes to associate the occurrence of BV with fetomaternal complications. The association was developed through comparison of women with BV with those without BV. The impact of BV on fetal health was assessed through birth weight of the child. All the data was periodically recorded for analysis. Women were classified into three age groups to predict the effect of increasing age on frequency of BV Statistical analysis: SPSS version 18 was used for statistical analysis. The data were presented as frequency and percentages. The student's t-test was used for estimating significance among the patients' categories. A p-value less than 0.05 was considered statistically significant.

#### **RESULTS**

Out of a total of 250 women, 48(19.2%) were diagnosed positive for bacterial vaginosis alone while in 0.8% and 2% cases BV was found along with trichomonas vaginitis and candidiasis, respectively. Candidiasis was the second-largest reported infection among the analyzed women affecting 4.8% of women (Table 1).

We have then analyzed the women with BV only and found that the occurrence rate of BV was significantly higher in women aged between 18-25 years. Moreover, nulliparous women and those belonging to lower social class had significantly higher positivity rates or BV. However, gestational age had a significant effect on the occurrence rate of BV (Table 2).

Table 3 presents the pregnancy outcomes among three study groups: BV, intermediate BV, and non-BV, classified according to the Nugent scoring technique. Abortion, preterm labor, premature rupture of membranes (PROM), and puerperal pyrexia were the most considerable adverse outcomes and were

significantly higher in the BV group. The women positive for BV had a significantly higher positivity rate for UTI than those without UTI (15 out of 48(31.2%) vs 18 out of 195(9.2%), p=0.001)

Table 1: Vaginal infection (n=250)

Vaginal infections	Frequency	P-value
Bacterial vaginosis	48 (19.2%)	0.001
Bacterial vaginosis and Trichomonas vaginalis	2 (0.8%)	NS
Bacterial vaginosis and Candidiasis	5 (2%)	NS
Candidiasis	12 (4.8%)	NS
Other infections	0 (0%)	-

NS=non-significant

Table 2: Demographic data of women positive for BV only (n=48)

Variables	Frequency (%)	P-value			
Age					
18-25	26 (54.1%)	0.01			
26-34	15 (31.2%)	NS			
>35	7 (14.5%)	NS			
Parity					
P0+0	18 (37.5%)	0.03			
P1+1	13 (27%)	NS			
P1+2	11 (22.9%)	NS			
P1+3	6 (12.5%)	NS			
Socio-economic star	tus				
Upper	3 (6.25%)	NS			
Middle	18 (37.5)	NS			
Lower	27 (56.2%)	0.004			
Gestational age at the time of investigation (weeks)					
11-20	16 (33.3%)	NS			
21-30	18 (37.5%)	NS			
31-40	14 29.1%)	NS			

Table 3: Pregnancy outcomes (n=250)

Adverse outcomes	BV positive (n=48)	Intermediate BV (n=7)	Non-BV (n=195)	P-value
Maternal outcomes				
Abortion	3 (6.25%)	0 (0%)	1 (0.51%)	0.03
PROM	13 (27%)	0 (0%)	5 (2.5%)	0.001
Preterm labor	21 (43.7%)	0 (0%)	14 (7.17%)	0.02
Puerperal pyrexia	2 (4.1%)	0 (0%)	1 (0.51%)	0.03
Fetal outcomes				
Birth weight				
2.5 kg	18 (37.5%)	5 (71.4%)	80 (41%)	NS
2-2.5 kg	28 (58.3%)	2 (28.5%)	100 (51.2%)	NS
<2.5kg	2 (4.1%)	0 (0)	15 (7.6%)	NS

### **DISCUSSION**

Our study revealed that 19.2% of women were positive for BV only whereas 0.8% and 2% of women were positive for BV with trichomonas vaginalis and BV with candidiasis, respectively. Candidiasis was the other major infectious agent that affected 4.8% of pregnant women. Our data on incidence rate complies with the previous study conducted by Lata et al on the Indian population. The study concluded a significantly high occurrence rate of BV that was found to be positive in 23.1% of analyzed women<sup>8</sup>. Similarly, Mechado et al. Evaluated 150 pregnant women and diagnosed BV in 17.3% of women<sup>9</sup>. However, contrasting results have also been reported in earlier studies. For instance, Cristiano et al. conducted a large-scale study on over a thousand Italian women and reported a BV occurrence rate as low as 4.9%10. Similarly, Gratacos et al. conducted a Spain-based study and found a BV occurrence rate of only 4.5%11. A study in Nigeria also reported 11.1% prevalence which can be justified by the inclusion of only symptomatic women<sup>12</sup>.

The incidence in our study was found significantly higher in women within the age bracket of 18-25 years, primipara, and the ones belonging to lower socioeconomic status. These results comply with the results of a randomized prospective study conducted by Akinbiyi and his colleagues who found that BV-positive cases were majorly young within the age bracket of 21-30 years<sup>13</sup>. Hay et al. described in their study that the incidence rate

of BV reduces with an increase in gestational age <sup>14</sup>. It can also be assumed that with increasing age, the infection becomes chronic and leads to the absence of clue cells in response to an immune reaction. Yen et al. associated sexual experience with the risk of occurrence of BV<sup>15</sup>. However, Morris and his coworkers found BV to be more common in women aged above 25 years <sup>16</sup>. The significant association of BV with socioeconomic status found in our study is in line with the results reported by Kamga and his coworkers. According to them, rural women were having a significantly higher incidence rate of BV<sup>17</sup>.

Our study found a significant correlation of BV with adverse pregnancy outcomes. Obstetric complications such as PROM, Puerperal pyrexia, abortion, and fetal consequences (prematurity) were significantly higher in women with BV. The exact cause mechanism behind premature infant's births by BV positive women but evidence support the hypothesis that BV results in upper vaginal tract infection that leads to premature birth<sup>18</sup>. Moreover, pregnant women with BV have increased cervical or vaginal levels of interleukin-1 $\beta^{19}$ , sialidase<sup>20</sup>, mucinase, and endotoxin<sup>21</sup>. This provoked an inflammatory response to infection along with a reduced amount of vaginal lactobacilli<sup>22</sup> further creating conditions for preterm birth<sup>23</sup> or even abortion.

Our study incidence of UTI was significantly higher in women with BV. BV and UTI have already been established as coexisting conditions<sup>24</sup>. In a study conducted by Afrakhteh and Mahdavi, who compared women with BV with healthy subjects, a significant

correlation of BV and UTI was found which complies with our  $\mbox{data}^{25}.$ 

Our study proves the previous hypothesis that the treatment of BV is not fully effective in preventing adverse pregnancy effects as the women tested positive for BV were treated with clindamycin which has been regarded as an effective treatment<sup>26</sup>. It may be explained by the fact that when the women were treated the inflammatory reactions resulting in complications had already been started. Until now no study has reported that treatment in early trimesters can reduce these adverse effects, therefore, proper treatment is yet to be found by future research.

#### CONCLUSION

The Bacterial vaginosis is significantly higher in pregnant women and is associated with adverse pregnancy outcomes such as abortion, preterm labor, puerperal pyrexia, and PROM.

#### Conflict of interest: Nil

**Limitation:** The study is limited in terms of study design and length. Therefore, it is suggested to conduct a multi-center study with a longer follow-up duration to assess the post-partum effects of BV.

**Author's contribution: SMM** conceived, designed and did statistical analysis, **PAAM** did data collection and manuscript writing, **SM** did review and final approval of manuscript, **SPAM** did editing of manuscript

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