

"Cytological Findings of Bacterial Vaginosis in Routine Pap Smears" A Two Yrs Institutional Study

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Abstract:-

Introduction = The healthy vaginal microflora is constituted mainly by Gram-positive bacilli .Other non-beneficial microbial species are also present in small numbers, but are not sufficient to cause disease. Among genital infections, Bacterial Vaginosis (BV) is one of the most common cause of vaginal disorder in women of childbearing age between 15-45 years contributing to more than 60% of all vulvovaginal infections.

Aims And Objectives:1.To study the spectrum of cytological findings of Bacterial Vaginosis in routine pap smears.2.To evaluate clinical diagnostic criteria in Bacterial vaginosis.3.To compare the cervical cytology findings with gram staining of pap smears in Bacterial Vaginosis.

Material And Methods : The present cross sectional study conducted over two years(November 2015 to October 2017)period comprised of 100 patients who were diagnosed as BV on pap smear in cytopathology department kakatiya medical college, WARANGAL.

Discussion : The present study showed maximum number of cases were recorded between 20-30 years age group. Out of 100 cases studied, pap smear showed only Bacterial Vaginosis in 54%,BV was associated with inflammation in 38% and erosion in 8%. 51cases presented with homogenous watery discharge,31 cases with mucoid white discharge and curdy white discharge was seen in 19 cases. According to Amsel's criteria,51 cases showed homogenous discharge, Ph>4.5 was seen in 91cases,whiff test was positive in 80 cases and clue cells were seen in 89 cases. Distribution of BV according to Nugent's score on gram staining showed 85% of cases with abnormal vaginal flora with a score of (7-10),10% cases showed intermediate flora with a score of (4-6) and 5% cases showed normal flora with a score of (0-3). Nugent's score showed a sensitivity of 96.25% , specificity of 60%,positive predictive value of 90.59% and negative predictive value of 80% when compared with Amsel's criteria which showed a sensitivity of 90.59%,specificity of 80%, positive predictive value of 96.25% and negative predictive value of 60% for diagnosing BV.

Conclusion: Bacterial vaginosis (BV) is the most common cause of vaginal discharge among women in reproductive age, characterized by an increased vaginal pH and the replacement of vaginal lactobacilli with Gardnerella vaginalis and anaerobic Gram negative rods.

Pap smear is the most simple and a quick test which is beneficial in diagnosing cervical infections like Bacterial vaginosis. Control of these infections is possible through regular screening and treatment. Early diagnosis of BV can help prevent further complications, by commencing appropriate treatment. By using Amsel's clinical criteria and Nugent's scoring ,BV can be diagnosed effectively in Pap smears. However, further studies need to be undertaken with inclusion of other ancillary tests for more confirmatory diagnosis

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I. Introducción

The healthy vaginal microflora is constituted mainly by Gram-positive bacilli of the genus Lactobacillus, the most common species being L. crispatus, L. iners, L. gasseri, and L. jensenii . However, other non-beneficial microbial species including Gardnerella vaginalis, Enterococcus species and Prevotella species can be present in small numbers, not sufficient to cause disease. Notably, lactobacilli play a crucial role in maintaining the health of female genital tract while preventing genitourinary infections.¹

Among genital infections, Bacterial Vaginosis (BV) is one of the most common cause of vaginal disorder in women of childbearing age between 15-45 years contributing to more than 60% of all vulvovaginal infections.²

While the etiology of BV is not clear, the menstrual cycle, concomitant infections, sexual activity, contraceptive methods and antibiotic use have all been implicated. Afflicted women are mostly asymptomatic, but some complain of a watery grey discharge with a fishy smell. Diagnosis is important as BV has been associated with serious health problems including pre-term birth, spontaneous abortion, pelvic inflammatory disease, endometritis and acquisition and transmission of several sexually transmitted infections like herpes

simplex virus type-2 (HSV-2), Trichomonas vaginalis, Neisseria gonorrhoeae and HIV.³High prevalence and the associated complications make BV an important public health issue. Due to the great diversity and complexity of microorganisms involved, the BV etiopathogenesis is not yet fully understood.⁴ Empirical treatment, based only on clinical criteria, leads to misdiagnosis and wrong treatment hence needs to be evaluated by correlation with proper lab diagnosis.

In our study cervical cytology findings are compared with gram staining of pap smears for diagnosing Bacterial Vaginosis. Early screening, diagnosis and treatment of Bacterial Vaginosis may be helpful in preventing complications

AIMS AND OBJECTIVES: **1.**To study the spectrum of cytological findings of Bacterial Vaginosis in routine pap smears.**2.**To evaluate clinical diagnostic criteria in Bacterial vaginosis.**3.**To compare the cervical cytology findings with gram staining of pap smears in Bacterial Vaginosis.

II. Material And Methods

The present cross sectional study conducted over two years (November 2015 to October 2017) period comprised of 100 patients who were diagnosed as bacterial vaginosis on pap smear in cytopathology department Kakatiya Medical College, Warangal .

Inclusion Criteria: **1.**Women with age group between 15 - 45yrs. **2.**Patients diagnosed as BV on pap smear according to Bethesda system for reporting cervical cytology.

Exclusion Criteria: **1.** Patients less than 15yrs & more than 45yrs. **2.**Patients negative for BV on pap smear.

Sample Collection And Diagnosis: Pap smears were collected from patients by the Gynecology department. The smeared slides were fixed by immersing it in 95% ethanol for a minimum of 15 minutes and were sent to cytopathology for Pap stain. The Bethesda system for reporting cervical cytology was used for diagnosing Bacterial vaginosis. Smear satisfying all three criteria:

1. Presence of coccobacilli flora
2. Presence of clue cells
3. Absence of lactobacilli flora were diagnosed as BV on pap smear.

One slide was sent to Microbiology department for Gram staining .The smear was then evaluated for the following morphotypes under oil immersion (1000x magnification): large Gram-positive rods (lactobacillus morphotypes), small Gram-variable rods(G vaginalis morphotypes), and curved Gram-variable rods (Mobiluncus species morphotypes).The results were graded using Nugent's criteria for diagnosis of BV. They were each graded on a scale of 0-10 and scores are then calculated as 0-3 (Normal), 4-6 (intermediate), and 7-10 (Bacterial Vaginosis).

Wet mount was done and examined under microscope for clue cells. More than 20 percent of the epithelial cells that have stippled appearance due to adherent coccobacilli and whose edges were obscured or appeared fuzzy on the wet mount were considered as clue cells. A clinical evaluation sheet noting the patients name, medical record number and date of examination along with a checklist of clinical findings was filled out. Results of Amsel's criteria(discharge,pH,KOH test,wet mount) and Pap smear tests were compared with Nugent's criteria and statistical analysis was done.

III. Statistical Analysis

Data was entered using Microsoft Excel 2010 version and analyze using Epi-Info version 7. Data was summarized in percentages and proportions. Appropriate statistical tests were applied wherever required with significance level at 5% & p<0.05 considered statistically significant. Screening tests which included sensitivity, specificity, positive predictive value and negative predictive values were used by the following formulas

Sensitivity: $a / (a+c) \times 100$,

Specificity: $d / (b+d) \times 100$ Positive,

predictive value: $a / (a+b) \times 100$

Negative predictive value: $d / (c+d) \times 100$

Where a=True positive,

b= False positive,

c= False negative ,

d= True negative

Ethical clearance has been obtained from Ethical Committee of kakatiya medical college/Mahatma Gandhi memorial Hospital, warangal.



Fig: PH scale with grading

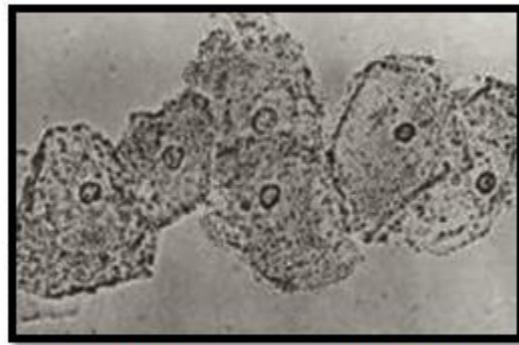


Fig: Wet mount showing clue cells 40X

IV. Observations And Results

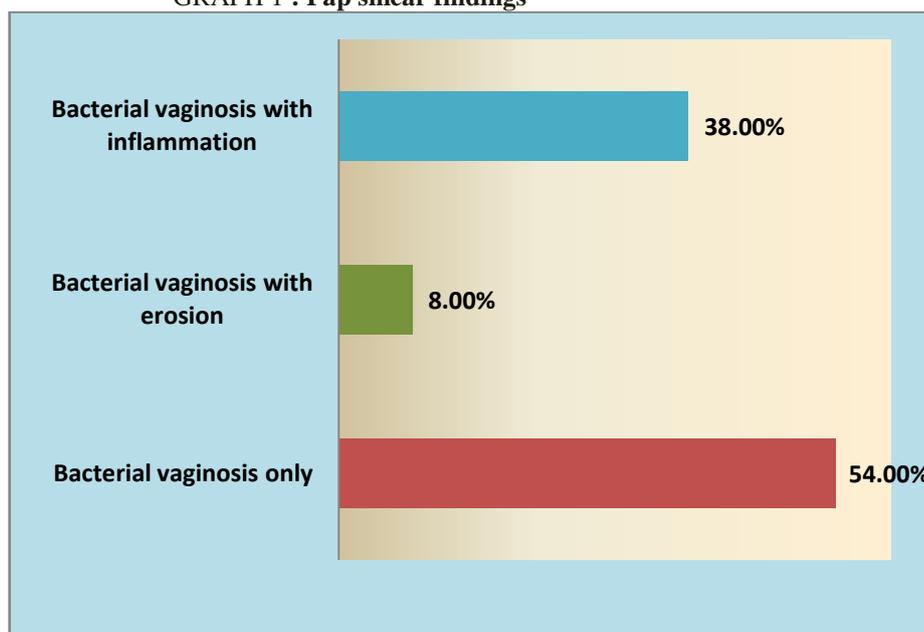
The present study of "Cytological findings of Bacterial Vaginosis in routine Pap smears" was carried out in Department of Pathology, kakatiya medical college ,warangal. The study sample consisted of 100 cases of pap smears sent for cytopathology department which were diagnosed as Bacterial Vaginosis. **Age distribution:** Out of 15-45years age group of study population, more cases were recorded between 20-30years of age . Mean age= 33.01±7.16

TABLE 1:- : Age wise distribution of the patients

Age groups (years)	Frequency (N=100)	Percentage
20-30	43	43%
31-40	40	40%
>40	17	17%
Total	100	100%

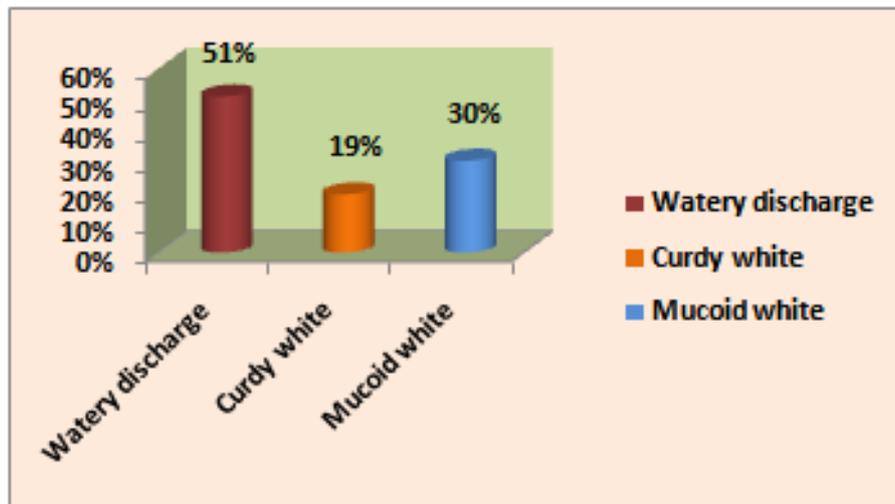
Pap smear findings:- Out of 100 cases studied, majority of cases(54%) showed only Bacterial vaginosis and only some cases were associated with inflammation or erosion .

GRAPH 1 : Pap smear findings



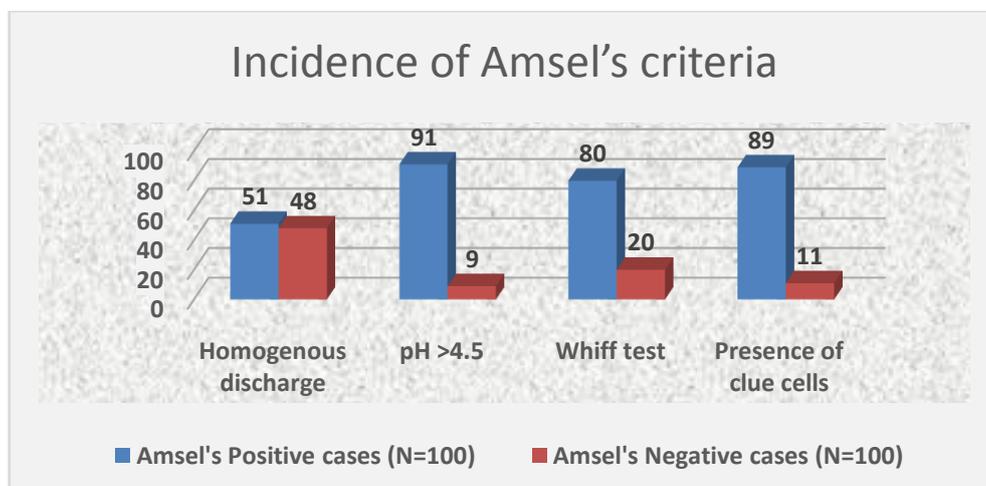
Vaginal discharge characteristics: Maximum number of cases showed watery discharge(N=100)

GRAPH 2 : Vaginal discharge characteristics



Incidence of Amsel's criteria: 51 cases showed homogenous discharge, Ph was >4.5 in 91cases, Whiff test was positive in 80cases and clue cells were seen in 89 cases

GRAPH 3: Incidence of Amsel's criteria



Efficacy of tests for diagnosing Bacterial Vaginosis by using Amsel's criteria: Sensitivity of homogenous discharge was 51%, Ph>4.5 was 92.5%, whiff test was 83.7% and clue cells was 91.3%

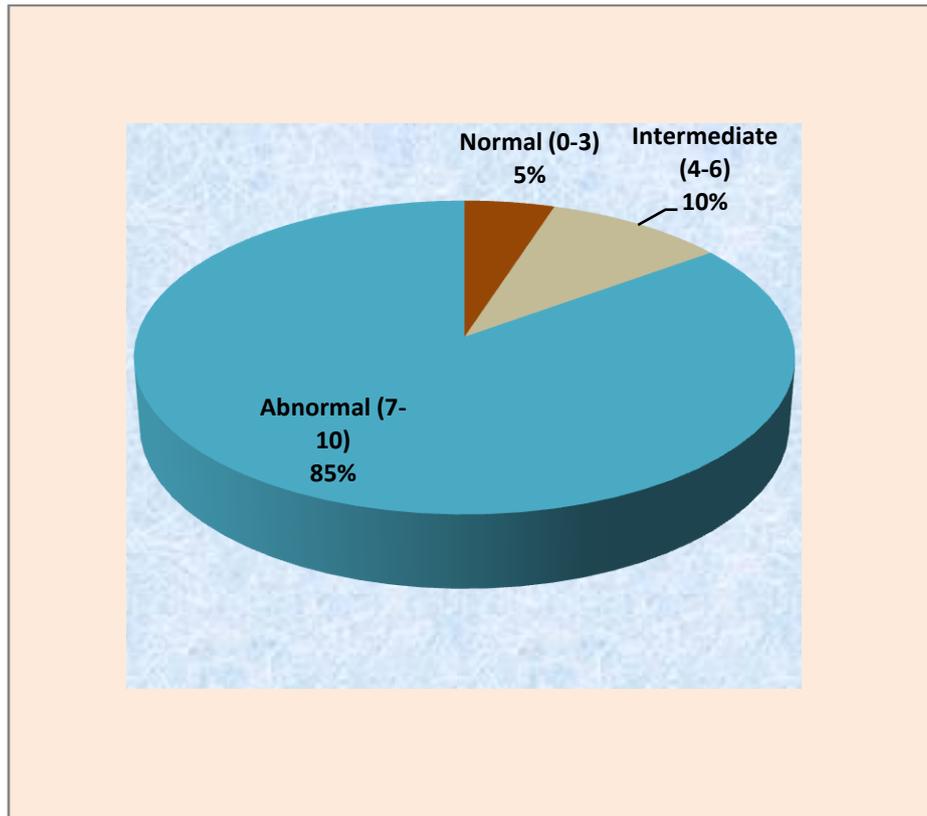
Table 2: Efficacy of tests for diagnosing Bacterial Vaginosis by using Amsel's criteria

Parameters	Vaginal pH>4.5	Discharge	Whiff test	Clue cells
Positive cases number	91	51	80	89
Sensitivity	92.5%	51%	83.7%	91.3%
Specificity	--	--	62.5%	37.5%
Positive Predictive value	96.7%	92%	96.2%	94.4%
Negative predictive value	--	--	25%	27.3%

Distribution of Bacterial vaginosis according to Nugent score:

Maximum number of cases(85%) showed abnormal vaginal flora according to Nugents score

GRAPH 4: Distribution of Bacterial vaginosis according to Nugent score



Comparison between Nugent’s score and Amsel’s criteria:

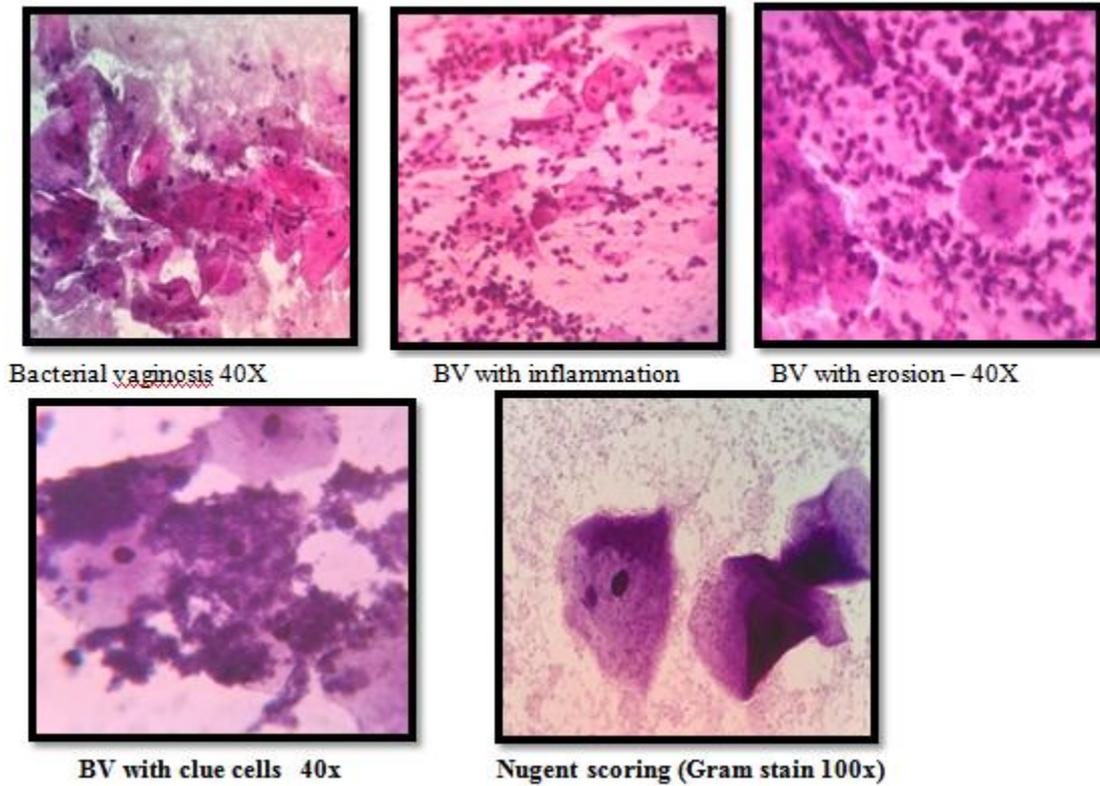
Nugent’s score showed a sensitivity of 96.25% and specificity of 60%.Amsel's criteria showed a sensitivity of 90.59% and specificity of 80%

Table 3: Comparison between Nugent’s score and Amsel’s criteria for diagnosis of BV

	Amsel’s Positive	Amsel’s Negative	Total
Nugent’s positive	77	08	85
Nugent’s Negative	03	12	15
Total	80	20	100

p=0.000001 (p<0.05 statistically significant)

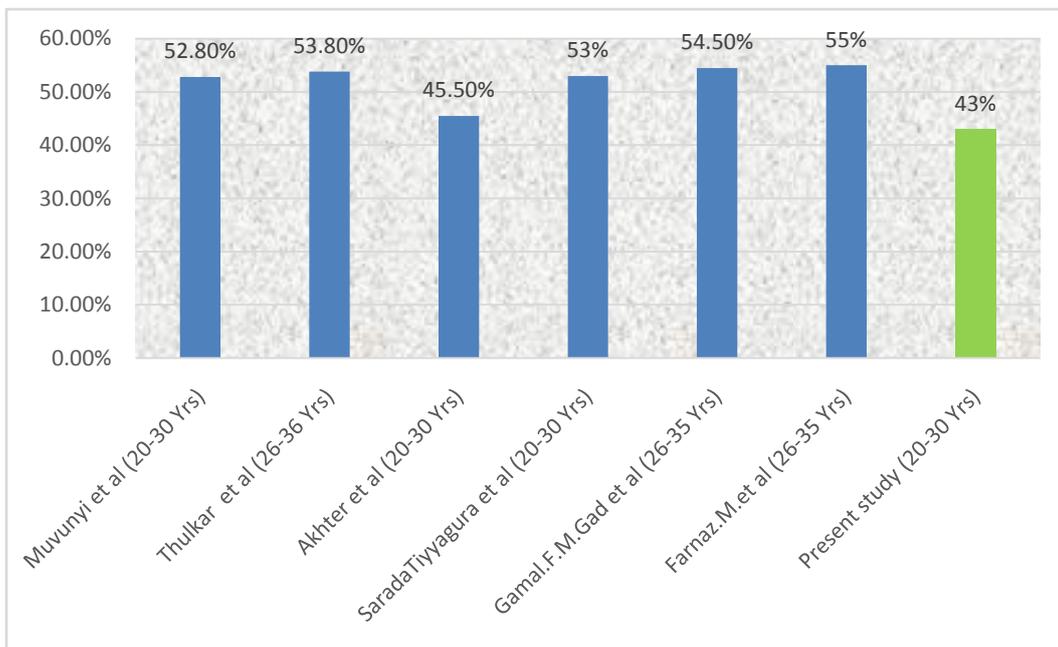
	Nugent criteria	Amsel’s criteria
Sensitivity	96.25%	90.59%
Specificity	60%	80%
Positive predictive value	90.59%	96.25%
Negative predictive value	80%	60%



V. Discussion

Bacterial Vaginosis cases diagnosed on routine pap smears were studied for Amsel's clinical criteria and Nugents scoring in gram staining. Total 100 cases were studied and results were recorded and compared with other studies.

GRAPH 5 : Incidence of Bacterial Vaginosis according to age distribution in various studies



In present study the highest incidence of BV was observed in age group of 20-30yrs with 43% as seen in. Our findings are comparable to the other mentioned studies. This was closest to a study done by **Akhter et al⁵** where incidence of BV in the same age group was 45.50% .In a study done by **Thulkar et al⁶** it was 53.8% and in a study done by **Gamal.F.M.et al⁷** it was 54.50%.These findings confirm that mostly women of child bearing age were affected by BV.

In a study by **Muvunyi et al⁸** the overall prevalence of bacterial vaginosis was 17.8% and the highest percentage of 52.8 % was found in the age group of 21-30 years compared with the lowest percentage of 1.9% in the age group less than 20 years.

Farnaz.M.et al⁹ reported that prevalence of bacterial vaginosis was highest in the age group of 20-30 years.In a study by **Sarada Tiyyagura et al¹⁰** a significantly high incidence was found in the age group of 21-30 years indicating that vaginosis is very common in the early reproductive years.

Bacterial Vaginosis cases are mostly associated with inflammation and erosion.

In present study, cytological spectrum of BV in pap smears showed 54% of cases with Bacterial vaginosis only,8% cases showed BV with erosion and 38% cases showed BV with inflammation

Table 4 :Cytological spectrum of BV in pap smears

Pap smear findings	No.(%)
Bacterial vaginosis only	54 (54%)
Bacterial vaginosis with erosion	08 (8%)
Bacterial vaginosis with inflammation	38 (38%)

In a study by **Lamont R. F.et al¹¹** pap-staining of vaginal smears is shown to be a useful instrument for diagnosing BV compared with the Amsel clinical criteria as well as with the mean Nugent score, in Gram stained smears. With regard to diagnostic accuracy, very little difference is found among the three staining methods when the same scoring system is used to compare the different staining methods in many countries.

Narasimha.A.et al¹² reported that pap smears have a sensitivity and specificity of 90% and 97% respectively.

Pap-stained vaginal smears can be used as a wholly adequate alternative to Gram-stained smears for BV diagnosis. It has been suggested that the presence of clue cells on the Pap smear agrees reasonably well with clinical criteria. So Pap smear test which is a simple, quick, painless procedure employed to screen cervical cancer can also be used for diagnosing cervicovaginal infections.⁴⁵

Raina.A.et al¹³ in their study reported that pap smear had a sensitivity of 61.0% and a specificity of 97.6%.Pap smear is moderately sensitive for screening of BV and because of its high specificity it is of diagnostic value when it is positive.

Schnadig et al¹⁴ reported a high correlation between pap smears and Gram smears for diagnosis of BV. Inflammation on pap smear has been associated with a 30–50% incidence of bacterial vaginosis.

Davis et al¹⁵ reported that compared to Gram stain, cervical cytologic test results had a sensitivity of 55%,specificity of 98%,positive predictive value of 96% and negative positive value of 78%. **Tokyo.C.et al¹⁶** reported that pap smear had a sensitivity of 43.1,specificity of 93.6, positive predictive value of 73.8, and negative predictive value of 79.8. for the diagnosis of Bacterial Vaginosis. Compared to the microbiological test results, Pap smear is not sensitive enough for screening of bacterial vaginosis. However, because of its high specificity, it may be an adequate diagnostic criteria when it is positive.⁴⁹

In a study by **John D. Davis et al¹⁷** pap smears had a sensitivity of 55% and a specificity of 98%,positive predictive value of 96% and negative predictive value of 78%. Compared to Gram stain of vaginal secretions, the cervical Pap smear has fair sensitivity (55%) and excellent positive predictive value (96%) in diagnosing bacterial vaginosis.

Karani.A. et al¹⁸ reported that sensitivity of pap smear was 59.4% and specificity was 83.3%.BV is associated with inflammatory changes on cervical smear in 47% of women.

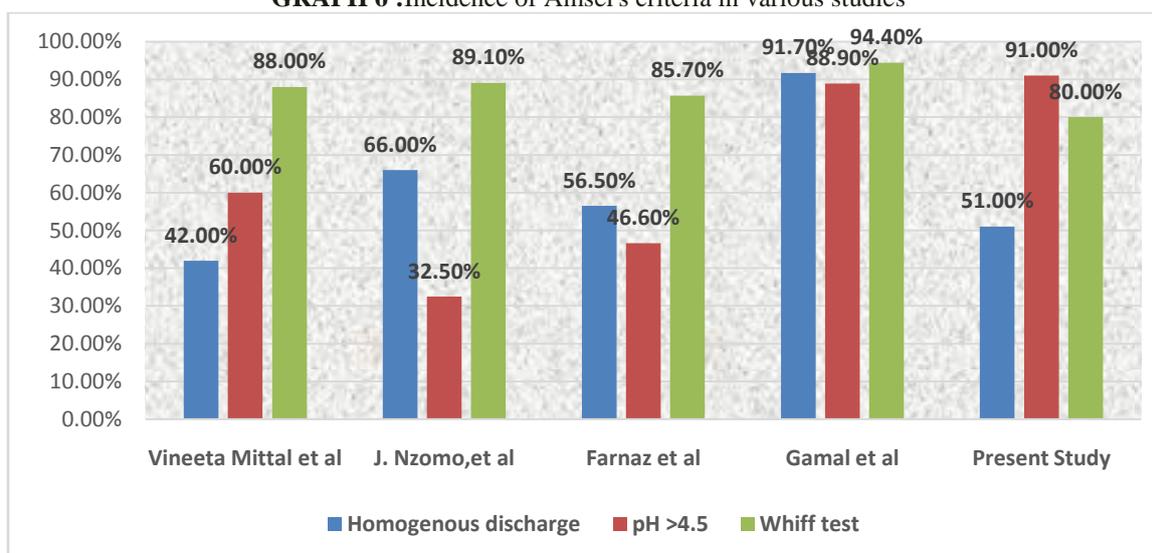
Donder et al¹⁹ reported that Prevalence of BV was higher in the inflammatory smear group, thus supporting that women with an inflammatory smear are more likely to harbour genital tract infection than women whose smear shows no evidence of inflammation. Previous studies demonstrated that women with no inflammatory changes on cervical smears can also harbour genital tract pathogens.Inflammation on Pap smear had a relatively low predictive value for the presence of vaginal pathogens in asymptomatic women. A high rate of BV was found both in women with inflammatory changes and in those without inflammatory changes on pap smear, suggesting that inflammation on pap smear is a poor indicator of cervical infection. Pap smears are less specific because standardized criteria for evaluation of Pap smears has not been routinely applied.

Amsel's criteria is the most common method of identifying BV.Patients were diagnosed as having Bacterial Vaginosis if they fulfilled any three of the following four criteria:

1. Thin, homogenous watery vaginal discharge.
2. Vaginal pH above 4.5.

3. A fishy smell on addition of 10% KOH to vaginal fluid (Whiff's test).
4. Presence of clue cells on saline wet mount.

GRAPH 6 :Incidence of Amsel's criteria in various studies



In present study 51% of cases presented with homogenous watery discharge, 91% with Ph>4.5, 80% with fishy odour and 89% with presence of Clue cells on cytology examination. Kurki.T. et al²⁰ reported that Amsel's criteria was the most common method of identifying BV in the past; however, there are inherent difficulties with each of the individual parameters like : Assessment of vaginal pH lacks specificity because an increase in vaginal pH may be a consequence of many other lower genital tract conditions, While vaginal pH normally falls between 3.8 and 4.2, it can change based on the activity of vaginal microflora.⁵⁴ In a study by Vineeta Mittal et al²¹ homogenous discharge was found in 42% of cases, Ph>4.5 was found in 60% and whiff test was positive in 88%.

Gamal et al⁷ reported in their study that 66.0% cases showed homogenous discharge, Ph>4.5 was seen in 88.9%, whiff test was positive in 94.4% and presence of clue cells was seen in 94.4%.

In a study by Farnaz et al⁹ homogenous discharge was seen in 56.55% of cases, Ph>4.5 was seen in 46.6%, whiff test was positive in 85.7% and presence of clue cells was seen in 77.3%.

J.Nzomo et al²² reported homogenous discharge in 66.0%, Ph>4.5 was seen in 32.5%, 89.1% of cases showed presence of clue cells. In present study sensitivity of vaginal Ph was 92.5%. In addition to BV, trichomoniasis, cervical secretions, contact with semen, and application of lubricant gels can increase vaginal pH. Therefore, combining pH tests with other symptoms can enhance the accuracy of the test in diagnosis of various infectious conditions. In present study whiff test has a sensitivity of 83.7% and specificity of 62.5%. In a study by Hallen et al²³ whiff test sensitivity was 33.9% and a specificity of 86.9%. They evaluated clinical criteria on individuals presenting at clinics for sexually transmitted diseases. They found positive whiff test results in 95% cases. However, Amsel's method can be highly subjective with regards the description of the discharge and the olfactive component ('whiff' test). In present study presence of clue cells in vaginal wet mount had sensitivity of 91.3% and specificity of 37.5%. This is similar to a study by Mohammadzadeh F et al,²⁴ the sensitivity of clue cells was calculated as 97.6%. Simoes et al²⁵ reported the high sensitivity 86% of these cells in the diagnosis of BV. Other studies have confirmed the presence of clue cells in vaginal discharge of 93% of patients with BV. Likewise, Islam et al²⁶ affirmed the high sensitivity of clue cells in BV diagnosis.

Identification of clue cells may vary according to the skill and interpretation of the microscopist and quality of sample collection. The demonstration Clue cells in wet mount was found in significantly higher numbers (90.5%) in women with bacterial vaginosis (P<0.001, positive predictive value 90.4%) while low sensitivity and positive predictive value were seen for vaginal discharge for detecting infection with bacterial vaginosis (p> 0.05, positive predictive value 26.0%). In a study by Bhat.G. et al²⁷ the most sensitive and specific individual Amsel's criterion was clue cells. Amsel's criteria with the lowest sensitivity and specificity were whiff test and vaginal pH respectively. Combination of clue cells with vaginal pH test were the highest in sensitivity while whiff test with clue cells were the highest in specificity than the other combined two Amsel's criteria. And concluded that Amsel's criteria for diagnosis of bacterial vaginosis can be simplified by using a combination of the two criteria, vaginal pH and clue cells, in settings where time or Gram staining is not available.

Table 5: Comparison of sensitivity and specificity of Amsel's criteria in various studies

Author(S)	Amsel's sensitivity	Amsel's specificity
Modak.T et al ²⁸	66.67%	94.74%
Udaya laxmi et al ²⁹	78%	95.6%
Taj.Y. et al ³⁰	77%	91%
Khatoon. R. et al ³¹	69%	93.1%
Sura I. A.Jabuk et al ³²	91%	76%
Gamal et al ⁷	88%	89.6%
Rajeshwar.s.et al ³³	78.72%	92.35%
Present study	90.58%	80%

In a study done by **Modak.T.et al²⁸** sensitivity was 66.67% and specificity was 94.74%. In a study by **Udaya laxmi et al²⁹** the sensitivity and specificity of Amsel's criteria were respectively 96.5% and 78.0%. Study done by **Taj.Y.et al³⁰** showed sensitivity of 77% and specificity of 91%. In a study done by **Khatoon.R.et al³¹** sensitivity was 69% and specificity was 93.1%. In present study sensitivity of Amsel's criteria was 90.58% and specificity was 80%, which was similar to a study done by **Sura I.A.Jabuk et al³²** where sensitivity was 91% and specificity was 76%. **Gamal et al⁷** reported sensitivity of Amsel's criteria as 88% and specificity as 89.6%. **Rajeshwar.s. et al³³** reported sensitivity and specificity of Amsel's criteria as 78.72% and 92.35% respectively.

BV is often misdiagnosed using clinical criteria because the components are subjective and dependent on the acuity of the clinician and available equipment. Nugent's scores based on bacterial morphotypes can assess the degree of alteration in vaginal flora and allow for standardized interpretation.

Nugent's standardized scoring system of gram stained vaginal smears provides a 0- to 10-point scale for the evaluation of vaginal flora, based on a weighted sum of the bacterial morphotypes. Nugent's score (0-3) is considered normal, (4-6) as intermediate and (7-10) is considered as BV.

Table6: Comparison of sensitivity and specificity of Nugent's score with other studies

Author(s)	Nugent's Sensitivity	Nugent's Specificity
Thomason.JL.et al ³⁴	97%	66.2%
Schwebke.JR.et al ³⁵	89%	83%
Sura I. A. Jabuk et al ³²	81%	75%
Present study	96.25%	60%

In present study sensitivity and specificity of Nugent's criteria was 96.25% and 60% respectively, which was similar to a study by **Thomason JL et al³⁴** with Nugent's sensitivity of 97% and specificity of 60% as shown in (Table 18 & Figure 19).

In a study by **Schwebke JR et al³⁵** sensitivity of Nugent's criteria is 89% and specificity is 83%. However in a study done by **Sura I.A.Jabuk et al³²** sensitivity of Nugent's score was 81% and specificity was 75%. There is a significant variation in the specificity values of Nugent's scoring. These differences may be due to difference in the geographical distribution, hygienic measures and sexual habits between the research areas. Nugent's standardized score had improved intercenter reliability ($r = 0.82$) compared with the Spiegel criteria ($r = 0.61$). The results of their study indicate that criteria for the diagnosis of bacterial vaginosis by using the Gram stain can be reproduced reliably between different centers and microbiologists. Nugent's score can help in avoiding over-diagnosis of BV and further over treatment of patients and further reduce the cost of treatment.³⁰ **Saharan SP et al³⁶** reported that Gram stain provides a simple and inexpensive method for laboratory confirmation of bacterial vaginosis where facilities for using the compound clinical criteria are not available.

Rangari et al³⁷ in their study reported Nugent's scoring system had a higher sensitivity in diagnosing BV while Amsel's criteria had less sensitivity and higher specificity. They concluded Amsel's criteria without utilizing staining methods could be misleading. According to their study, by Amsel's criteria false positive were 26.4% (Because of the high specificity) while 1.2% cases of BV were missed. Thus Nugent's score can help in avoiding overestimating and further treatment of BV.

In studies of **Schwebke JR et al³⁵**, **Mastrobattista JM et al³⁸**, **Edward Demba et al³⁹** gram stain of vaginal fluid and use of Nugent's criteria to identify a case of BV has been shown to have a high sensitivity and specificity compared with Amsel's criteria (89 percent and 83 percent, respectively) and large number of true BV cases (by Nugent's score) were missed by the Amsel's method, limiting its utility as a BV diagnostic method.

A definitive advantage of gram staining is that it is more objective as slide can be stored for future reference. Gram staining although a reliable diagnostic method but is mostly performed in research studies because it is more cumbersome to use it in clinical practice than Amsel's criteria.

In present study, difficulties inherent in the Nugent method. Firstly, the interpretation of these smears is subjective because there is always uneven distribution of material on a dry smear and readings may be obtained from different parts of the slide. The microscopic area examined by an oil immersion objective is very small

relative to the area covered by the smear. Secondly, over decolourised smears make it difficult to discern the small gram- negative rods.

According to **Deborah B et al**⁴⁰ gram staining showed a sensitivity of 93% and specificity of 70%. Microscopic evaluation by Gram stain requires special diagnostic skills and therefore over diagnosis is common and therapy is frequently empirical. Although Nugent scoring system is the gold standard for diagnosing BV, it is underused because it is time consuming, and interpretation of gram stain requires experience. Culture is a very sensitive method with a very low specificity for the diagnosis of Bacterial vaginosis.

Udaylaxmi et al²⁹ reported that vaginal culture has a sensitivity of 88.7%, specificity of 51%, positive predictive value of 85.5% and negative predictive value was 58%. Diagnosis of BV by culture was least sensitive method. Culture is to be reserved and performed in treatment failure cases.

Shahzadi.N.et al⁴¹ reported that vaginal culture has got no role in the diagnosis of bacterial vaginosis therefore it is advised that Amsel's criteria may be used for the diagnosis.

Tokyo.c.et al¹⁶ reported that vaginal culture test results had sensitivity of 77.8%, specificity of 97.7%, positive predictive value of 93.3%, negative predictive value 91.4% for the diagnosis of Bacterial Vaginosis.

In a study by **Mason PR.et al**⁴² culture was positive in 91% cases. culture leads to over diagnosis and should not be used for directing therapy or as a test of cure after treatment because many women who harbour *G. vaginalis* usually lack any objective signs of BV. Therefore vaginal cultures may not be of any use in routine diagnosis of BV. However, culture plays a very important role in the history of BV and may continue to be useful in the identification of new BV-associated organisms and in research settings.⁸¹

In present study vaginal culture was not done due to cost limitation. This however did not affect the result interpretation as it has been observed that obtaining routine vaginal cultures in patients with BV has no utility because this is a polymicrobial infection.

VI. Conclusion

Bacterial vaginosis (BV) is the most common cause of vaginal discharge among women in reproductive age, characterized by an increased vaginal pH and the replacement of vaginal lactobacilli with *Gardnerella vaginalis* and anaerobic Gram negative rods.

Pap smear is the most simple and a quick test which is beneficial in diagnosing cervical infections like Bacterial vaginosis. Control of these infections is possible through regular screening and treatment. Early diagnosis of BV can help prevent further complications, by commencing appropriate treatment. By using Amsel's clinical criteria and Nugent's scoring, BV can be diagnosed effectively in Pap smears. However, further studies need to be undertaken with inclusion of other ancillary tests for more confirmatory diagnosis

References

- [1]. Borges S, Silva J, Teixeira P. The role of lactobacilli and probiotics in maintaining vaginal health. Archives of gynecology and obstetrics. 2014 ;289(3):479-89.
- [2]. Sobel, J. D. Bacterial vaginosis. Annu. Rev. Med. 2010;51, 349–356.
- [3]. Lamont RF, Sobel JD, Akins RA, Hassan SS, Chaiworapongsa T, Kusanovic JP, Romero R. The vaginal microbiome: new information about genital tract flora using molecular based techniques. BJOG: An International Journal of Obstetrics & Gynaecology. 2011;118(5):533-49.
- [4]. Schwabke JR, Muzny CA, Josey WE. Role of *Gardnerella vaginalis* in the Pathogenesis of Bacterial Vaginosis: A Conceptual Model. Journal of Infectious Diseases. 2014 ;210(3):338-43.
- [5]. Akhter S, Satter H, Tarafder S, Miah RA, Sharmin S, Ahmed S. Rapid detection of Bacterial Vaginosis (BV) by BVBlue test. Bangladesh Journal of Medical Microbiology. 2010;4(1):24-7.
- [6]. Thulkar J, Kriplani A, Agarwal N, Vishnubhatla S. Aetiology & risk factors of recurrent vaginitis & its association with various contraceptive methods. The Indian Journal of Medical Research. 2010;131(1):83.
- [7]. Gad GF. Evaluation of different diagnostic methods of bacterial vaginosis. IOSR Journal of Dental and Medical Sciences (IOSR-JDMS).;1(13):15-23
- [8]. Muvunyi CM, Hernandez TC. Prevalence of bacterial vaginosis in women with vaginal symptoms in South Province, Rwanda. African Journal of Clinical and Experimental Microbiology. 2009;10(3).
- [9]. Ferris MJ, Maszta A, Aldridge KE, Fortenberry JD, Fidel PL, Martin DH. Association of *Atopobium vaginae*, a recently described metronidazole resistant anaerobe, with bacterial vaginosis. BMC infectious diseases. 2004;4(1):1.
- [10]. Tiyyagura S, Taranikanti M, Ala S, Mathur DR. Bacterial vaginosis in indian women in the reproductive age group. International Journal of Biomedical Research. 2012;3(8):371-3
- [11]. Lamont RF, Hudson EA, Hay PE, Morgan DJ, Modi V, Ison CA, Taylor-Robinson D. A comparison of the use of Papanicolaou-stained cervical cytological smears with Gram-stained vaginal smears for the diagnosis of bacterial vaginosis in early pregnancy. International journal of STD & AIDS. 1999;10(2):93-7
- [12]. Narasimha A, Nirup NC, Chandhana B, Nishanth N, Harendra KM. Spectrum of infections in cervico-vaginal pap smears. J. Clin. Biomed. Sci. 2014;4(1):222-5.
- [13]. Raina A, Rawat A, Nasreen K, Talib V H, Tayal U. Pap Smears in the Diagnosis of Bacterial Vaginosis. Indian Medical Gazette. 2013; 147 (11): 417-419.

- [14]. Schnadig VJ, Davie KD, Shafer SK, Yandell RB, Islam MZ, Hannigan EV. The cytologist and bacterioses of the vaginal-ectocervical area. Clues, commas and confusion. *Acta cytologica*. 1988;33(3):287-97.
- [15]. Zhou X, Bent SJ, Schneider MG, Davis CC, Islam MR, Forney LJ. Characterization of vaginal microbial communities in adult healthy women using cultivation-independent methods. *Microbiology*. 2004;150(8):2565-73.
- [16]. Tokyol Ç, Aktepe OC, Cevrioğlu AS, Altunış M, Dilek FH. Bacterial vaginosis: comparison of Pap smear and microbiological test results. *Modern pathology*. 2004;17(7):857-60.
- [17]. Davis JD, Connor EE, Clark P, Wilkinson EJ, Duff P. Correlation between cervical cytologic results and Gram stain as diagnostic tests for bacterial vaginosis. *American journal of obstetrics and gynecology*. 1997;177(3):532-57
- [18]. Karani A, De Vuyst H, Luchters S, Othigo J, Mandaliya K, Chersich MF, Temmerman M. The Pap smear for detection of bacterial vaginosis. *International Journal of Gynecology & Obstetrics*. 2007;98(1):20-3.
- [19]. Donders GG, Vereecken A, Salembier G, Van Bulck B, Spitz B. Assessment of vaginal lactobacillary flora in wet mount and fresh or delayed Gram's stain. *Infectious diseases in obstetrics and gynecology*. 1996;4(1):2-6.
- [20]. Kurki T, Sivonen A, Renkonen OV, Savia E, Ylikorkala O. Bacterial vaginosis in early pregnancy and pregnancy outcome. *Obstetrics & Gynecology*. 1992;80(2):173-7.
- [21]. Vineeta Mittal, Amita Jain, Yashodhara Pradeep Development of modified diagnostic criteria for bacterial vaginosis at peripheral health centres in developing countries *J Infect Dev Ctries* 2012; 6(5):373-377.
- [22]. Nzomo J, Waiyaki P, Waihenya R. Bacterial Vaginosis and Correlates in Women of Reproductive Age in Thika, Kenya. *Advances in Microbiology*. 2013;3(3):249-54.
- [23]. Hallen A, Pählson C, Forsum U. Bacterial vaginosis in women attending STD clinic: diagnostic criteria and prevalence of *Mobiluncus* spp. *Genitourinary medicine*. 1987;63(6):386-9.
- [24]. Mohammadzadeh F, Dolatian M, Jorjani M, Majd HA. Diagnostic value of Amsel's clinical criteria for diagnosis of bacterial vaginosis. *Global journal of health science*. 2015;7(3):8
- [25]. Simoes JA, Discacciati MG, Brolazo EM, Portugal PM, Dini DV, Dantas MC. Clinical diagnosis of bacterial vaginosis. *International Journal of Gynecology & Obstetrics*. 2006;94(1):28-32.
- [26]. Islam A, Safdar A, Malik A. Bacterial vaginosis. *JPMA*. 2009;59(9):601.
- [27]. Bhat, G., Kotigadde, S., & Shenoy, S. (2011). Comparison of the methods of diagnosis of BV. *Journal of Clinical and Diagnostic Research*, 5(3), 498-501.
- [28]. Modak T, Arora P, Agnes C, Ray R, Goswami S, Ghosh P, Das NK. Diagnosis of bacterial vaginosis in cases of abnormal vaginal discharge: comparison of clinical and microbiological criteria. *The Journal of Infection in Developing Countries*. 2010;5(05):353-60.
- [29]. Udayalaxmi BG, Kotigadde S, Shenoy S. Comparison of the methods of diagnosis of bacterial vaginosis. *Journal of Clinical and Diagnostic Research*. 2011;5(3):498-501.
- [30]. Taj Y, Nasir D, Kahkashan N, Anjum A. Sensitivity and specificity of rapid clinical diagnostic test for bacterial vaginosis and its analytical value. *J Dow Uni Health Sci* 2012; 6(3):91-94.
- [31]. Khatoun R, Jahan N, Ahmad S, Rabbani T. Comparison of OSOM BV Blue test with conventional methods for diagnosis of bacterial vaginosis. *African Journal of Microbiology Research*. 2013;7(28):3698-703.
- [32]. Jabuk SI, Hussian RS, Jabuk SI. Different method for diagnosis bacterial vaginosis in married woman in Hilla city. *IOSR Journal of Dental and Medical Sciences (IOSR-JDMS)*.;1(13):46-51.
- [33]. Rajeshwar Rao S et al., Diagnosis of Bacterial Vaginosis: Amsel's Criteria vs Nugent's scoring Sch. *J. App. Med. Sci*. 2016; 4(6C):2027-2031.
- [34]. Thomason JL, Gelbart SM, Anderson RJ, Walt AK, Osypowski PJ, Broekhuizen FF. Statistical evaluation of diagnostic criteria for bacterial vaginosis. *American journal of obstetrics and gynecology*. 1990;162(1):155-60.
- [35]. Schwebke JR, Hillier SL, Sobel JD, McGregor JA, Sweet RL. Validity of the vaginal gram stain for the diagnosis of bacterial vaginosis. *Obstet Gynecol*. 1996;88:573-6.
- [36]. Saharan SP, Surve C, Raut V, Bhattacharya M. Diagnosis and prevalence of bacterial vaginosis. *Journal of postgraduate medicine*. 1993;39(2):72.
- [37]. Rangari AA, Singh P, Sharma VK. Comparison of the Amsel's Composite Clinical Criteria and Nugent's Criteria For Diagnosis of Bacterial Vaginosis:-A Step Towards Preventing Mis-Diagnosis. *Journal Of Advance Researches In Biological Sciences (A Peer Reviewed Indexed Medical Journal)*. 2013;5(1):37-44.
- [38]. Mastrobattista JM, Bishop KD, Newton ER. Wet smear compared with gram stain diagnosis of bacterial vaginosis in asymptomatic pregnant women. *Obstetrics & Gynecology*. 2000;96(4):504-6.
- [39]. Demba E, Morison L, Van der Loeff MS, Awasana AA, Gooding E, Bailey R, Mayaud P, West B. Bacterial vaginosis, vaginal flora patterns and vaginal hygiene practices in patients presenting with vaginal discharge syndrome in The Gambia, West Africa. *BMC infectious diseases*. 2005;5(1):1.
- [40]. Nelson DB, Hanlon A, Nachamkin I, Haggerty C, Mastrogiannis DS, Liu C, Fredricks DN. Early Pregnancy Changes in Bacterial Vaginosis-Associated Bacteria and Preterm Delivery. *Paediatric and perinatal epidemiology*. 2014;28(2):88-96
- [41]. Neelam S, Sohail I. Rapid Clinical Diagnostic Tests for Bacterial Vaginosis and its Predictive Value. *Int J Pathol*. 2010;8:50-2
- [42]. Mason PR, Gwanzura L, Latif AS, Marowa E. Genital infections in women attending a genito-urinary clinic in Harare, Zimbabwe. *Genitourinary medicine*. 1990;66(3):178-81

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