

Prevalence of aerobic bacterial vaginosis among chronic IUD users among Egyptian women's

Abstract

Objective: The aim of this study is to detect the prevalence of bacterial vaginosis among copper T380 IUD users among Egyptian women.

Patients and methods: This cross sectional study was conducted on 100 patients attended family planning outpatient clinic. Two vaginal discharge samples were obtained. The first swab was examined for detection of clue cells. Vaginal PH and amine test to fulfill Amsel criteria. The second swab was assessed using Nugent's criteria

Results: significant difference between the study group regarding Amsel criteria. there was a significant association between presence of Foul-smelling discharge (either as a symptom or as a sign) and diagnosis of BV there was a significant relation between vaginal discharge and Amsel criteria all negative vaginal discharge cases show negative Amsel criteria ($p < 0.05$).

Conclusion: We concluded that IUD use significantly increased the risk of BV among Egyptian women's and Women who use IUD as contraceptive method should seek medical help if they complain of abnormal vaginal discharge.

Keywords: IUD, bacterial vaginosis, IUD users, infertility, foul-smelling discharge, vaginal cuff cellulitis, symptomatic, birth control, late miscarriage, levonorgestrel, exacerbated

Volume 8 Issue 6 - 2019

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Received: November 29, 2019 | **Published:** December 11, 2019

Abbreviations: IUD, intrauterine contraceptive device; BV, bacterial vaginosis; STIs, sexually transmitted infection; UTI, urinary tract infection; PID, pelvic inflammatory disease; KOH, potassium hydroxide; SPSS, statistical package for social sciences; OR, odds ratios

Introduction

Bacterial vaginosis (BV) can be considered as the commonest vaginal infection and is the cause of many complications, such as preterm birth and transmission of sexually transmitted infection (STIs),¹ and it has been associated with vaginal cuff cellulitis, wound infection and abscess formation after hysterectomy.² BV is associated with increased rates of obstetrical complications, such as preterm labor, and low birth weight, preterm premature rupture of the membranes, late miscarriage, spontaneous abortion, Chorioamnionitis, postpartum maternal infections and infertility.³ BV may be symptomatic or asymptomatic. Symptomatic BV is characterized by a copious, thin, homogeneous, milky, foul-smelling vaginal flow, which is exacerbated after intercourse without condom use and menstruation.⁴

There are two gold standards diagnostic method is used to diagnose BV. The first diagnostic method is Amsel clinical criteria and the second is the laboratory-based Nugent Gram staining evaluation.⁵ An Intrauterine device (IUD) is a contraceptive device which is T shaped device and may contain copper or levonorgestrel which is inserted into the uterine cavity. It is along acting, reversible contraception with a high efficacy on birth control. Failure rate with copper IUDs is about 0.8% in first year of its use.⁶ IUDs in 2007 were the commonest reversible contraception with a use of more than 18million users worldwide.⁶ The prevalence of BV varies according to age, race or ethnicity, education, and poverty.⁷ The aim of this study is to detect the prevalence of bacterial vaginosis among copper T380 IUD users among Egyptian women.

Patients and methods

This a cross sectional study was conducted at Obstetrics and Gynecology department at Menoufia university hospital, Menoufia governorate, Egypt and Al Amiriyah general hospital, Alexandria governorate, Egypt when 100 patients attended family planning outpatient clinic in the period between March 2017 till June 2017 . The local ethical committee at Menoufia University hospital approved the study protocol and an informed consent was obtained from all the Patients. After exclusion of women with active PID, Patient with UTI, Menstruating patients at the time of clinic visit, recent coitus or douching, Usage of antimicrobial therapy or any vaginal local drugs within 72h. We included women aged 18years to 40years IUD user since at least 1year, sexually active female, Non-pregnant women, Women who presented with abnormal vaginal discharge, Women who presented with abnormal vaginal odour, Women who presented with Pruritus vulvae.

Women who attended the family planning clinic for routine checkup for copper T380 were assessed for presence of inclusion and exclusion criteria through detailed history taking and examination .Patients that fulfilled the criteria and were accepted to participate in the study were recruited and subjected to

Local examination: Inspection of vulva, urethra, and perineum to detect any discharge or local inflammatory signs. We inserted a vaginal speculum, lubricated with water only and evaluated the vaginal discharge. Vaginal discharge samples were obtained with two dry cotton-wool tipped swabs from the lower third of the vaginal wall: The first swab was spread on clear glass slide for wet mount preparation; the slide was examined by microbiologist for detection of clue cells. Vaginal PH was measured directly in the discharge on the removed speculum by dipping a pH indicator strip with a scale graded from 1-14 including distinct color key for each value. After

removal of the speculum we added two drops of 10% potassium hydroxide (KOH) to the posterior lip of the speculum (amine test). The release of fishy odor means positive amine test. These measures were performed to fulfill Amsel criteria. The second swab was spread on a clear glass slide for gram staining; the slides were left to dry in air then transferred to the microbiologist. We fixed slides by heating and stained by gram stain. This was assessed using Nugent's criteria system as follows: Morphotype were counted as the average number of bacteria under oil immersion (x1000 magnification).

0=no morphotype present, 1+=<1 morphotype present, 2+=1 to 4 morphotype present, 3+=5 to 30 morphotype present, 4+=>30 morphotype present. The amount of each morphotype detected on the smear was graded and then allocated a score was interpreted as follow: A slide with a total score of 7 was interpreted as "BV". A slide with a total score of 4 to 6 was interpreted as "Intermediate flora." A slide with a total score of 0 to 3 was interpreted as "Normal flora" (non-BV).

Statistical methods

Statistical analysis and figures were performed using Microsoft® Excel® version 2010 and Statistical Package for Social Sciences (SPSS®) for Windows® version 15.0. Data were described as range, mean and standard deviation (for numeric parametric variables), range, median and interquartile range (for numeric non-parametric or discrete variables), or number and percentage (for categorical variables). Association between categorical variables and dichotomous outcome was estimated using binary logistic regression analysis and expressed in terms of odds ratios (OR) and their 95% confidence intervals. Diagnostic validity was expressed in terms of sensitivity, specificity, positive and negative predictive values, as well as likelihood ratios. Significance level was set at 0.05.

Results

Table 1: represent non-significant difference between the study patients as regarding Age, Parity, Duration of marriage, Occupation, Duration of IUD insertion.

Table 2: shows significant difference between the study group regarding Amsel criteria.

Table 3: represent highly significant relation between Nugent's score category and Amsel criteria ($P<0.05$).

Table 4: revealed significant difference between the studied patients as regarding Whiff test, $\text{PH}<4.5$, vaginal discharge, pruritis, clue cells and use of douche. This table shows a significant statistical difference between the study patients as regarding culture and type of bacteria.

Table 5: show that there was significant relation between age and Amsel criteria ($P<0.05$).

Table 6: represent no statistical significant relation between application of IUD category and Amsel criteria ($P>0.05$).

It was found that there was a significant relation between $\text{pH}>4.5$ and Amsel criteria, from 23cases $\text{PH}>4.5$, 22 of them had +ve Amsel criteria ($p<0.05$). There was a significant relation between Whiff test and Amsel criteria all the positive whiff test cases was positive Amsel criteria ($p<0.05$). There was a significant relation between clue test and Amsel criteria, the 75 negative cases clue test show negative Amsel criteria ($p<0.05$). Negative Amsel criteria was 54(69.2%)

and positive was 9(40.9%) at negative pruritis. At positive pruritis was 24(30.8%) and 13(59.1%) respectively. There was statistical significant relation between pruritis and Amsel criteria ($P<0.05$), this could be attributed to presence of mixed infection as presence of pruritis is pathognomonic to candidal infection. Negative Amsel criteria were 35(44.9%) and positive was none at negative culture. At positive culture was 43(55.1%) and 22(100%) respectively. There was highly a statistical significant relation between culture and Amsel criteria ($P<0.05$).

Positive use of douche was 51(51%) and negative use of dough was 49(49%) Negative Amsel criteria was 36(46.2%) and positive was 13(59.1%) at negative use of douche. At positive use of douche was 42 (53.8%) and 9 (40.9%) respectively so, there was no statistical significant relation between use of douche and Amsel criteria ($P>0.05$). Negative Amsel criteria was 67(85.9%) and positive was 20 (90.9%) at negative pelvic pain. At positive pelvic pain was 11(14.1%) and 2(9.1%) respectively. Negative Amsel criteria was 64(82.1%) and positive was 18(81.8%) at negative vaginal dyspareunia. At positive vaginal dyspareunia was 14(17.9%) and 4(18.2%) respectively. There was no statistical significant relation between pelvic pain and vaginal dyspareunia and Amsel criteria ($P>0.05$).

Table 1 Demographic features of the studied group

Characteristics	n=100	Percentage (%)
Age	24	24
<25 years	38	38
25-30	38	38
30+		
Range	17.00-43.00	
Mean	28.86	
S.D	6.092	
Duration of marriage	37	37
< 5 yrs	47	47
10-May	16	16
10+		
Range	2.00-22.00	
Mean		
S.D	6.89	
	4.426	
Occupation		
No	57	57
Yes	43	43
Duration of IUD insertion	46	46
1 year	31	31
2 yrs	23	23
3+		

Table Continued

Characteristics	n=100	Percentage (%)
Range	.00-10.00	
Mean		
S.D	4.74	
	3.404	
Parity	32	32
1	32	32
2	36	36
3.00+		

Table 2 Distribution of the studied group regarding Amsel criteria

Amsel criteria	Frequency	Percent
-ve	78	78
+ve	22	22
Total	100	100

Table 3 Nugent's score category in relation to Amsel criteria

Nugent's score category	Amsel criteria	Total	
		-ve	+ve
1	No.	50	0
	%	64.10%	0.00%
2	No.	13	0
	%	16.70%	0.00%
3	No.	15	22
	%	19.20%	100.00%
Total	No.	78	22
	%	100.00%	100.00%
X2		48.025	
P		0.0001**	

Table 4 Distribution of the studied group regarding Clinical criteria, culture and type of bacteria and symptoms

Clinical criteria	n= 100		Culture and type of bacteria			Symptoms	
	n= 100	%	%	%	%	n= 100	%
Whiff test	78	78	Culture			No Symptoms	
-ve	22	22	-ve	35	35	-ve	74
+ve			+ve	65	65	+ve	26
PH>4.5	77	77	S.Aureus			Pelvic Pain	
-ve	23	23	-ve	88	88	-ve	87
+ve			+ve	12	12	+ve	13
Vaginal discharge	62	62	E.coli			Vaginal Dyspareunia	
-ve	38	38	-ve	83	83	-ve	82
+ve			+ve	17	17	+ve	18
Pruritis	63	63	K. Pneumonia			Vaginal Discharge	
-ve	37	37	-ve	86	86	-ve	78
+ve			+ve	14	14	+ve	22
Clue test	75	75	P. Mirabilis				
-ve	25	25	-ve	90	90		
+ve			+ve	10	10		
Use of douche	49	49	B. Subtilis				
-ve	51	51	-ve	90	90		
+ve			+ve	10	10		
			A.israelii				
			-ve	97	97		
			+ve	3	3		

Table 5 Age group in relation to Amsel criteria

Age group		Amsel criteria		Total
		-ve	+ve	
<25 years	No.	22	2	24
	%	28.20%	9.10%	24.00%
25-30	No.	32	6	38
	%	41.00%	27.30%	38.00%
30+	No.	24	14	38
	%	30.80%	63.60%	38.00%
Total	No.	78	22	100
	%	100.00%	100.00%	100.00%
X2		8.345		
P		.015*		

Table 6 Application of IUD category in relation to Amsel criteria

Duration of IUD category		Amsel criteria		Total
		-ve	+ve	
1 year	No.	36	10	46
	%	46.20%	45.50%	46.00%
2 yrs	No.	24	7	31
	%	30.80%	31.80%	31.00%
3+	No.	18	5	23
	%	23.10%	22.70%	23.00%
Total	No.	78	22	100
	%	100.00%	100.00%	100.00%
X2		0.009		
P		0.996		

There was a significant association between presence of Foul-smelling discharge (either as a symptom or as a sign) and diagnosis of BV there was a significant relation between vaginal discharge and Amsel criteria all negative vaginal discharge cases show negative Amsel criteria ($p < 0.05$). There was no significant relation between the Amsel criteria and phase of menstrual cycle ($p > 0.05$), where negative Amsel was 23(29.5%) in follicular phase and it was 55 (70.5%) in luteal phase. positive Amsel was 9 (40.9%) in follicular phase and it was 13(59.1%) in luteal phase. As regarding Duration of marriage, Negative Amsel criteria was 31(39.7%) and positive was 6(27.3%) at duration <5 years. At 5-10 years was 37(47.4%) and 10(45.5%). At 10+ duration was 10(12.8%) and 6 (27.3%) respectively. There was no significant relation between duration of marriage and Amsel criteria ($P > 0.05$).

Discussion

Lactobacilli are the dominant normal vaginal flora. In patients with BV the lactobacilli decrease in concentration and may disappear, while anaerobic and facultative anaerobic organisms increase in concentration.⁸ Bacterial vaginosis (BV) is the considered the commonest vaginal infection among women in reproductive age. Many studies showed that use of an IUD has been associated with

BV. This may be due to the tail of the IUD which might favor vaginal growth of anaerobic and facultative anaerobic organisms. In addition, the presence of BV during the IUD insertion could also lead to an increased risk of complications in the first 3months of use including PID.⁹ In clinical practice, Amsel clinical criteria are the most commonly used criteria. The diagnosis is positive for BV if at least three out of the four criteria are fulfilled. These criteria are: Presence of a typical discharge, PH>4.5, Positive whiff test, Presence of clue cells in the wet smear.¹⁰ Our study consisted with the previous studies who reported that majority of the cases of BV were within the age group of 26-35 and demonstrated that Age above 40 years old was risk factor for BV. This may be attributed to the premenopausal hypo estrogenic condition at that age. Declining levels of estrogen causes elevated vaginal PH, and the age group 20-40 had the highest prevalence of BV followed by the age group above 40.¹¹⁻¹³

We founded that the percent of positive Amsel criteria decrease with increasing duration of use. That was in accordance to the study that was done by Sura Abed Jabuk.,¹³ that showed that the relationship between positive culture and the duration of use IUD. During the 1st year, 21(42%) of IUD users had positive culture, while the negative culture reached up to 2(4%) among the IUD users.¹³ These

findings are similar to other studies, which showed high incidence of other bacterial infections among IUD users during the first year after insertion with significant decrease of this type of bacteria after 36 month of IUD.¹⁴ Our results consistent with the results published by Sura Abed Jabuk.,¹³ who reported that the isolated organisms was the pathogenic bacteria *E.coli* (16%), followed by *S. Aurous* and *K. Pneumonia* (12%), then *B. subtilis*, *P. mirabilis*, *A. israelii* is 10%, 8%, 6% respectively from all positive results.¹³ These findings are similar to many studies, which have been conducted to detect the bacteria that adhere to IUD, and colonize the vagina and cervix during IUD use. In one study *E.coli* was the most common microorganism.¹⁵ Kampan et al.,⁸ reported that the vaginal douching increased the incidence of bacterial vaginosis. This may be due to that vaginal douche lead to change of the vaginal ecosystem, and this consistent with our results.⁸

According to the study done by Sura Abed Jabuk.,¹³ there were only 18% of women in the study are asymptomatic, they were almost equally. The commonest symptom was abnormal vaginal discharge (a total of 50 women).¹³ Our study consistent with the study done by Kampan et al.,⁸ and Ocyiyanti et al.,¹² there was a significant agreement between diagnosis of BV based on Amsel criteria and diagnosis of BV based on Nugent score ($=0.695$, $p<0.001$).⁸⁻¹² The association between BV and IUD use and has been unclear. Some studies reported an increase risk of BV in IUD users, and should be screened prior to IUD insertion, but others reported no association.^{15,16}

Conclusion

We concluded that IUD use significantly increased the risk of BV and Women who use IUD as contraceptive method should seek medical help if they complain of abnormal vaginal discharge and they should be screened for BV and if they wish to get pregnant after removal of the IUD they should be treated from BV even if they are asymptomatic to decrease BV complications during pregnancy.

Strength of the study

Our study is promising for screening of BV with easily available and applicable toll; accordingly such women's if they wish to get pregnant after removal of the IUD they should be treated from BV even if they are asymptomatic to decrease BV complications during pregnancy.

Limitations of the study

Inability to recruit a large cohort and to design a multicenter trial was unintended limitation of current study.

Acknowledgments

The authors would like to acknowledge the contribution of residents and nursing staff at obstetrics and gynecology department of Menoufia University hospital and Al Amiriyah general hospital.

Conflicts of interest

The authors declare that there are no conflicts of interest.

Funding

None.

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