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HEALTHCARE-ASSOCIATED BACTERIAL VAGINOSIS AFTER GYNECOLOGICAL SURGERIES AND ASSOCIATED ADVERSE PREGNANCY OUTCOME IN UKRAINE

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ABSTRACT

The aim: To determine the prevalence of healthcare-associated bacterial vaginosis after gynecological surgeries and associated adverse pregnancy outcomes in Ukraine.

Materials and methods: Multicenter retrospective cohort study was conducted from January 2019 to December 2021 in eleven medical centers from eight regions of Ukraine. Vaginal cultures were obtained preoperatively from 3,502 women undergoing gynecologic surgery. Diagnosis of Bacterial Vaginosis is based on the Nugent and Amsel criteria.

Results: Healthcare-associated bacterial vaginosis (HA BV) was diagnosed in 1,498 of 3,502 women, giving a prevalence rate of 42.8%. HA BV was significantly associated with preterm birth (risk ratio [RR], 2.68; 95% confidence interval [CI], 1.44–4.98), miscarriage (RR, 6.11; 95% CI, 3.22–14.11), low birth weight (RR, 3.20; 95% CI, 1.29–7.94), and premature rupture of membranes (RR, 6.75; 95% CI, 3.11–14.67).

Conclusions: The HA BV after gynecological surgeries prevalence is high in Ukraine, with a concomitant adverse pregnancy outcome, including preterm birth, low birth weight, premature rupture of membranes, and miscarriage. A significant number of cases of bacterial vaginosis are associated with long-term use of antibiotics to treat post-operative infections.

KEY WORDS: Prevalence, healthcare-associated bacterial vaginosis, gynecological surgery, antibiotic use, pregnancy outcomes, Ukraine

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INTRODUCTION

Improving maternal and perinatal health is one of the biggest medical and public health challenges worldwide. Over the past decades, there have been increasing discussions on whether vaginal dysbiosis, the imbalance of the vaginal commensal bacterial communities (microbiota), influences pregnancy outcomes and should be monitored antenatally. Healthy vaginal microbiota (VMB) is crucial to the lower female reproductive tract. VMB contains a predominance of hydrogen-peroxide-producing *Lactobacillus* species that contribute to an immunological balance and therefore support a healthy reproductive tract.

Bacterial vaginosis (BV) is one of the most common vaginal dysbiotic conditions worldwide. BV constitutes a gynecological condition characterized by an alteration

of the vaginal microenvironment and more specifically an alteration of the normal *Lactobacillus*-dominated vaginal flora, to a flora that includes a variety of facultative and obligatory anaerobic bacteria. According to literature, general population prevalence of BV is high globally, ranging from 23% to 29% across regions (Europe and Central Asia, 23%; East Asia and Pacific, 24%; Latin America and Caribbean, 24%; Middle East and North Africa, 25%; sub-Saharan Africa, 25%; North America, 27%; South Asia, 29%). Within North America, black and Hispanic women have significantly higher (33% and 31%, respectively) prevalence compared with other racial groups (white, 23%; Asian, 11%). During pregnancy, the prevalence of BV varies from 11.7% to 49.0% while variability in prevalence exists between different races and/or ethnicities [1]. It remains unclear

whether these findings reflect genetic, socioeconomic, or behavioral discrepancies.

BV has been associated with increased risk of preterm delivery, first-trimester miscarriage in women undergoing in vitro fertilization, preterm premature rupture of membranes, amniotic fluid infections, chorioamnionitis, postpartum and postabortal endomyometritis as well as postabortal pelvic inflammatory disease [2, 3]. The estimated annual global economic burden of treating symptomatic BV is US \$4.8 (95% CI, 3.7-6.1) billion. The US economic burden of BV is nearly tripled when including costs of BV-associated preterm births and human immunodeficiency virus cases [1].

The pathogenesis of BV remains largely elusive, although some microorganisms, including *Gardnerella vaginalis*, are suspected of playing a role in the etiology of this disorder. Although various risk factors and pathogenetic mechanisms related to the development of BV have been described, its exact etiology remains unknown. The healthy vaginal flora is inhabited by a variety of *Lactobacillus* spp. (90–95% of total bacteria), such as *L. chrispatus*, *L. iners*, *L. jensenii*, *L. vaginalis*, and *L. gasseri* that maintain a low pH (<4.5), produce bacteriostatic and bactericidal substances and, as a result, impede the occurrence of infection [4]. A decrease in or absence of *Lactobacillus* spp. provokes an increase in the vaginal pH that leads to an overgrowth of anaerobic Gram-negative rods, leading to the development of BV [5]. The vaginal flora responsible for BV can either be transient or of a more permanent nature and consists of various microorganisms including *Gardnerella vaginalis*, *Prevotella* spp., *Porphyromonas* spp., *Bacteroides* spp., *Peptostreptococcus* spp., *Mycoplasma hominis*, *Ureaplasma urealyticum*, *Mobiluncus* spp., *Fusobacterium* spp., *Sneathia* spp., *Atopobium vaginae*, and *Clostridium* spp. [6, 7]. A polymicrobial biofilm on the epithelial cells of the vagina is a characteristic feature of BV [8].

Risk factors for BV mainly include hormonal changes, current or prior use of specific medication such as antibiotics and immunosuppressants [9], smoking as well as women's hygiene behavior, i.e., vaginal douching and sexual habits, such as the number of sexual partners [10], age of first sexual encounter, use of an intrauterine device [1, 11]. In Ukraine clinicians often overprescribe antibiotics pre-surgery and post-surgery sometimes for several days after gynecological surgery. However, the number of cases of healthcare-associated infections after gynecological surgeries is not decreasing [12-14]. This is often associated with multidrug-resistant strains of the responsible pathogens [15, 16]. Treatment of post-operative infections include the extended use of antibiotics. Long-term use of antibiotics to treat infec-

tions caused by multidrug-resistant pathogens can alter the vaginal flora. Studies evaluating healthcare-associated bacterial vaginosis after gynecological surgeries are currently lacking.

THE AIM

The aim this study to determine the prevalence of healthcare-associated bacterial vaginosis after gynecological surgeries and associated adverse pregnancy outcomes in Ukraine

MATERIALS AND METHODS

DESIGN, SETTINGS AND POPULATION

Multicenter retrospective cohort study was conducted from January 2019 to December 2021 and recruited 3,502 women (pregnant and non-pregnant) reproductive age, defined as ages 15 to 49 years undergoing gynecologic surgery. We compiled list of the 20 medical centers. However, only eleven medical centers from eight regions of Ukraine agreed to take part in our study. The study population included women had history of gynecological surgery for benign diseases who were local residents. Exclusion criteria included Chlamydial infections, Syphilis or other sexually transmitted bacterial infections, plans to move within the next 12 months, participation in a clinical trial using antibiotics or genital microbicides, and limitations preventing informed consent.

DATA COLLECTION

Data were obtained for the following variables: age, gravidity, parity, diagnosis, surgical procedure, preoperative and postoperative antibiotic use, complications, and postoperative BV. Each patient was identified only by a code to ensure confidentiality. Incident and clinical signs of BV, including cervical motion tenderness, uterine tenderness, and adnexal tenderness, were measured at each visit. As this was a time-to-event data analysis, women not developing BV contributed data until their last study visit. Participants were followed quarterly for approximately 12 months with clinical examinations and surveys. Our study includes interviews, questionnaires, and examinations medical records. Information was collected at baseline and each follow-up visit. Ambulatory medical records and relevant hospital records were reviewed for the all-women's. A data collection form was created to extract demographic, microbiological, and clinical data, and outcome information from routine patient records.

ETHICS

All participants gave written informed consent, and the study was approved by the institutional review boards of the Shupyk National Healthcare University of Ukraine; Ethics Committee approved this study.

MICROBIOLOGICAL METHODS

Vaginal cultures were obtained for nonpregnant patients undergoing gynecologic surgery, which included benign gynecologic, urogynecologic, and gynecologic oncology cases. At each visit, vaginal fluid was collected for vaginal smears. Gram stains were performed and categorized using the Nugent scoring method as low, intermediate, or high (0–3, 4–6, and 7–10, respectively) [17]. High Nugent scores are indicative of BV and for clarity are termed “Nugent-BV” [18]. Additionally, clinical diagnosis of BV was assessed using Amsel criteria (having 3 of the following clinician-assessed signs: thin homogeneous vaginal discharge, vaginal pH >4.5, the presence of a fishy odor upon adding potassium hydroxide solution to vaginal secretions, and/or clue cells on microscopy) [19]. Diagnosis by Amsel criteria has also been recently termed “Amsel-BV” [18]. Clinicians directly questioned women regarding vaginal symptoms (including vaginal discharge, irritation, itching, burning, foul odor, and other), and then coded those that met Amsel criteria for BV as “symptomatic BV” or “asymptomatic BV” based on their clinical judgement [18].

STATISTICAL ANALYSIS

In this study clinical and microbiological data were entered in an Excel (Microsoft Corp., Redmond, WA, USA) database for statistical analysis. We estimated pooled prevalence with a random effects model with inverse variance weights. We adjusted estimates of prevalence obtained by Amsel’s criteria using the formula and estimates of sensitivity and specificity relative to Nugent score [18]. We tested risk factors associated with incident Bacterial Vaginosis including Nugent category, Amsel-BV (both symptomatic and asymptomatic), and sociodemographic measures. We used χ^2 and Fisher exact tests for categorical factors, and Cochran–Armitage trend tests for ordinal factors. Cox proportional hazards models were used to test whether Nugent score and Amsel-BV with risk factors behaviors were associated with risk of incident BV. We generated both unadjusted models and models adjusted for all other factors. The proportional hazards assumption was assessed using scaled Schoenfeld residuals for all models. In this study statistical significance was defined as $P < 0.05$.

RESULTS

PREVALENCE OF BACTERIAL VAGINOSIS

During the study period (2019–2021), 1,498 of 3,502 women’s undergoing gynecologic surgery were found to have healthcare-associated bacterial vaginosis (HA BV). Of the total HA BV cases, 12.8% were asymptomatic. The prevalence of HA BV among participants this study was 42.8% (95% CI: 42.0–43.6). The prevalence of HA BV varied by type of gynecological procedure and antibiotic use. Characteristics of the study sample are summarized in Table I.

Most women (89%) received preoperative or perioperative antibiotics, with ceftriaxone alone (41%) and ceftioxin alone (33%) the most commonly given antibiotics. Forty one percent of the patients with HA BV had *Lactobacillus*-predominant vaginal microflora, 22.3% had an intermediate BV vaginal microflora, and 70.9% had a BV vaginal microflora. There were no statistically significant differences between the three BV groups with respect to age, invasiveness of the surgery, or use of preoperative antibiotics (Table I).

Table I describes relationships between operative characteristics and postoperative HA BV. Although the percentage of patients with HA BV was higher for procedures in which the vagina was entered than for other procedures (20.7% versus 37.7%), this difference was not statistically significant. HA BV was also more common in patients who received preoperative or perioperative antibiotics (89.3% versus 10.7%), but this difference was not statistically significant. The higher rate of HA BV associated with pre/perioperative and postoperative antibiotic use may reflect a tendency to use antibiotics in patients who are at higher risk of postoperative infection. No statistically significant difference was found between ceftriaxone alone, ceftioxin alone, and other antibiotics with respect to the HA BV (Table II). There was a statistically significant difference between the three BV groups with respect to postoperative HA BV ($P = 0.017$). Further significance testing found that the differences between the positive-BV group and the *Lactobacillus*-predominant group, and between the positive-BV group and the intermediate-BV group, with respect to postoperative HA BV, were statistically significant ($P = 0.045$ and $P = 0.007$, respectively). The difference between the intermediate BV group and the *Lactobacillus*-predominant group was not statistically significant ($P = 0.28$).

BACTERIAL VAGINOSIS AND PREGNANCY OUTCOMES

Of the 1,498 women who were positive for HA BV, 24.8% had preterm birth, 14.1% had low birth weight

Table I. Characteristics of women with healthcare-associated Bacterial Vaginosis (HA BV) after gynecological surgeries in Ukraine (2019-2021)

Characteristics	All women's		HA BV				P value
			Yes		No		
	n	%	n	%	n	%	
Age (years)							0.053
15-21	189	5.4	162	8.1	27	1.8	
22-26	311	8.9	297	14.8	14	0.9	
27-31	421	12.0	317	15.8	104	6.9	
32-36	784	22.4	468	23.4	316	21.1	
37-41	936	26.7	486	24.3	450	30.0	
42-49	861	24.6	274	13.7	587	39.2	
Peritoneum entry							0.086
Vaginal only	978	27.9	414	20.7	564	37.7	
Abdominal only	786	22.4	403	20.1	383	25.6	
Vaginal and abdominal	1,738	49.6	1,187	59.2	551	30.8	
Pre/perioperative antibiotics given	3,127	89.3	1,891	94.4	1,236	82.5	
Vagina not entered during procedure	1,480	42.3					0.11
Lactobacillus predominant	386	26.1	175	8.7	211	14.1	
Intermediate BV	311	21.0	194	9.7	117	7.8	
Positive BV	783	52.9	302	15.1	481	32.1	
Vagina entered during procedure	1,960	56.0					0.09
Lactobacillus predominant	684	34.9	273	13.6	211	27.4	
Intermediate BV	379	19.3	162	8.1	217	14.5	
Positive BV	897	45.8	316	15.8	581	38.8	
Preoperative antibiotics not given	375	10.7					0.057
Lactobacillus predominant	146	38.9	95	4.7	51	3.4	
Intermediate BV	68	18.1	31	1.5	37	2.5	
Positive BV	161	42.9	64	4.0	97	6.5	
Preoperative antibiotics given	3,127	89.3					0.024
Lactobacillus predominant	927	29.6	710	35.4	217	14.5	
Intermediate BV	909	29.1	588	29.3	321	21.1	
Positive BV	1,291	41.3	723	36.1	568	37.9	
Post-operative antibiotics given	2,189	62.5					0.0014
Lactobacillus predominant	136	6.2	85	4.2	51	3.4	
Intermediate BV	511	23.3	128	6.4	383	25.6	
Positive BV	1,542	70.4	355	17.7	1,187	79.2	
Total	3,502	100.0	2,004	57.2	1,498	42.8	0.05

(LBW), and 28.4% had premature rupture of membranes (PROM), and 26.6% had miscarriage. They had 2.7 times the risk of preterm birth (95% confidence interval [CI], 1.44–4.98), 3.2 times the risk of LBW (95% CI, 1.29–7.9), 6.8 times the risk of PROM (95% CI, 3.1–14.7), and 6.1 times the risk of miscarriage (95% CI, 3.22–14.1) compared with those who were negative (Table II).

DISCUSSION

To our knowledge, no study addressing to the prevalence of HA BV after gynecological surgeries and associated adverse pregnancy and birth outcomes. The present study showed that HA BV after gynecological surgeries is a common vaginal disease in women of reproductive age in Ukraine. The prevalence of HA BV among participants this study was 42.8%. Of the

Table II. Relationship among the presence of healthcare-associated bacterial vaginosis (HA BV) after gynecological surgeries and adverse pregnancy outcomes in Ukraine (2019-2021)

Pregnancy Outcome	HA BV				RR (95% CI)	P value
	Yes (n=1,498)		No (n=2,004)			
	n	%	n	%		
Preterm birth	371	24,8	186	9,3	2.68 (1.44–4.98)	0.002
Miscarriage	398	26,6	76	3,8	6.11 (3.22–14.11)	<.001
LBW	211	14,1	89	4,4	3.2 (1.29–7.94)	0.008
PROM	425	28,4	91	4,5	6.75 (3.11–14.67)	<.001

*BV, bacterial vaginosis; CI, confidence interval; LBW, low birth weight; PROM, premature rupture of membranes; RR, risk ratio.

total HA BV cases, 12.8% were asymptomatic. The prevalence of HA BV varied by type of gynecological procedure and antibiotic use. HA BV was significantly associated with preterm birth, miscarriage, LBW, and PROM. Of the 1,498 women who were positive for HA BV, 24.8% had

The prevalence rate of HA BV of 42,8% among pregnant women in this study is within the range of other recent studies, i.e., from 5.8% to 49% [1, 20–22]. It remains unclear whether these findings reflect genetic, socioeconomic, or behavioral discrepancies.

According to literature, risk factors for BV mainly include hormonal changes, current or prior use of specific medication such as antibiotics and immunosuppressants, and the existence of foreign bodies, such as cloth or toilet tissue in the vagina [9]. In our study a significant number of cases of bacterial vaginosis are associated with long-term use of antibiotics to treat post-operative infections.

Increasing evidence is suggesting that BV is associated with various adverse pregnancy outcomes, such as an increased risk of early and late miscarriage, PROM, LBW, and preterm birth [2, 20, 22–25]. The results of our study supported previous studies.

The treatment of HA BV may prevent post-operative infections after major gynecological surgery or surgical termination of pregnancy. Women undergoing hysterectomy, the surgical termination of pregnancy, should be screened for BV, and those who are positive should be treated. Asymptomatic pregnant women with previous preterm delivery may benefit from treatment, but the screening and treatment of these women remain controversial [2].

Our study showed that post-operative infection remains the common complication after gynecological procedures in Ukraine. Best practices should be established and followed to reduce the risk of post-operative infection associated with gynecologic surgery. Optimiz-

ing the antibiotic prophylaxis and empirical antimicrobial therapy may reduce the burden of postoperative infection in gynecological surgeries, but prevention is the key element [12-16].

The high cost of HA BV-associated sequelae highlights the need for research to understand potential causal linkages between HA BV and adverse health outcomes. Further research to determine the etiology of HA BV and corresponding prevention and sustainable treatment strategies are urgently needed to reduce the burden of BV among women.

STRENGTH AND LIMITATION

This is the first epidemiological study that focuses on the prevalence of healthcare-associated bacterial vaginosis after gynecological surgeries and adverse pregnancy and birth outcomes. The results of this study provide useful evidence for prevention efforts to decrease HA BV and its contribution to adverse pregnancy outcomes in Ukraine. The limitations of our study include its retrospective design and including 29.2% regions in Ukraine. Therefore, results this study may not be representative of other Ukrainian regions.

CONCLUSIONS

The present study showed that HA BV after gynecological surgeries prevalence is high in Ukraine, with a concomitant adverse pregnancy outcome, including preterm birth, low birth weight, premature rupture of membranes, and miscarriage. A significant number of cases of bacterial vaginosis are associated with long-term use of antibiotics to treat post-operative infections. The high cost of HA BV-associated sequelae highlights, further research is needed to determine the etiology and understand potential causal linkages between HA BV after gynecological surgeries, and adverse pregnancy and birth outcomes in female.

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