Prevalence of bacterial vaginosis in postmenopausal women in the state of Odisha, India

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Abstract: *Background:* Worldwide, only few reports are there to explain the prevalence of bacterial vaginosis (BV) as well as the association of various factors with BV in postmenopausal women. *Aims and Objectives:* To study the prevalence of BV and to analyze the association of various factors with BV in postmenopausal women in the state of Odisha, India. *Methods:* During recruitment, all the women completed a questionnaire containing socio-demographic features, medical and gynecological problems. A speculum examination of the vagina was done and a vaginal secretion was collected using BD BBL swabs for Gram staining. Diagnosis of BV was carried out by using Nugent's scoring method and a score of 4-10 was considered for abnormal or positive for BV. *Results:* A total of 209 postmenopausal women were recruited in this study with a median age of 54 years. As per the diagnostic criteria, the prevalence of BV was found to be 24.4%. The occurrence of BV was found to be associated with age of the women specially who were >55 years old (P=0.018), women with no formal education i.e. less than 5th standard (P=0.016), and women who were staying with 6 or more individuals in family (P<0.0001). Most of the postmenopausal women with BV were significantly associated with various clinical symptoms like abnormal vaginal discharge (P=0.001), itching/ burning of genitalia (P=0.011) and back pain (P=0.001). *Conclusion:* The association of various factors and clinical symptoms with BV found in this study may have implications in the health of postmenopausal women in India.

Keywords: Abnormal Vaginal Discharge, Bacterial Vaginosis, India, Post menopause, Nugent's Score.

Introduction

Menopause is a non-reproductive stage or end of the fertility due to decrease in the ovarian hormones, estrogen and progesterone level during the fourth or fifth decades of life. In the absence of these hormones, the vaginal mucosa becomes thin and starts to atrophy, becoming smaller and less elastic [1]. This environment of vagina was found to be more vulnerable to small tears during intercourse or masturbation leading to dyspareunia [2-3].

Due to the hormonal changes, post-menopausal women also experienced certain clinical abnormalities such as night sweats, hot flashes, decreased cognitive functions, and mood changes etc [4]. Globally, around 50% of post-menopausal women usually have vulvovaginal atrophy [5].

Changes in the vaginal environment during menopause lead to a change in the vaginal micro-biome. There is a decreased in the *Lactobacilli* population as well as production of lactic acid which leads to increase in the vaginal pH. With the increased pH, the vagina becomes susceptible to other infections triggering vulvovaginal atrophy with varied clinical signs and symptoms. There are very few reports on the prevalence and associated etiology of bacterial vaginosis (BV) in postmenopausal women worldwide. Globally, the prevalence of BV in postmenopausal women was found to be 6-50% [6-13]. However, there is paucity of literatures on the prevalence of BV in Indian postmenopausal women. This study was undertaken with an aim to access the prevalence as well as

association of various factors with BV in postmenopausal women residing in western part of Odisha state, India.

Material and Methods

Study design: This was a cross-sectional study based on a survey on postmenopausal women attending to the out-patient department (OPD) of Department of Obstetrics and Gynecology (O&G) of Veer Surendra Sai Institute of Medical Sciences and Research (VIMSAR), Burla, Odisha, India (coordinates: 21.50°N and 83.87°E). This institute is caters to population residing in western part of Odisha state and few from the eastern Chhattisgarh state. The patient recruitment was done from December, 2016 to November, 2018.

Sample size: As there was no specific study on the prevalence of BV in postmenopausal women in India, postmenopausal women attending to the clinic for various problems during the study period were considered for the study. The power of the study can be calculated post-hoc once this prevalence is accurately estimated by this study.

Study population: Postmenopausal women attending the O & G outpatient department with vaginal symptoms such as abnormal vaginal discharge, itching, burning, dysperunia, lower abdominal pain, back pain was considered. Postmenopause was considered if the women have experienced no menstruation since last 12 cycles. We excluded women who (1) were in the reproductive age groups; (2) were already undergoing treatment; (3) had a hysterectomy; (4) had taken a course of antibiotics during the previous three weeks; (5) had diabetes mellitus; (6) were HIV positive; (7) had any severe medical disorders requiring immediate referral to a higher level of health care; and/or (8) refused to be a part of this study.

Data collection: After taking written consent for the study, a pre-designed questionnaire developed and tested was asked to each woman [14]. The questionnaire contained the information regarding socio-demographic features like age, marital status, year of marriage, religion, education, occupation, number of family member and monthly income etc. Questionnaire on clinical symptoms included abnormal vaginal discharge (quantity, odor, color, and consistency), burning

or itching of the genitalia, and the presence of ulcers at vulva and labia, back pain, abdominal pain etc.

Collection of vaginal samples: A speculum examination of vagina and cervix was carried out by a trained O & G specialist, particularly to look for the presence of any cervical erythema, bleeding, inflammation, vaginal discharge, and ulcers at cervix. Vaginal specimens from posterior vaginal fornix were collected by using BD BBL swabs (BD, Maryland, USA). The swabs were used for both vaginal pH measurement and smear preparation for Gram's staining.
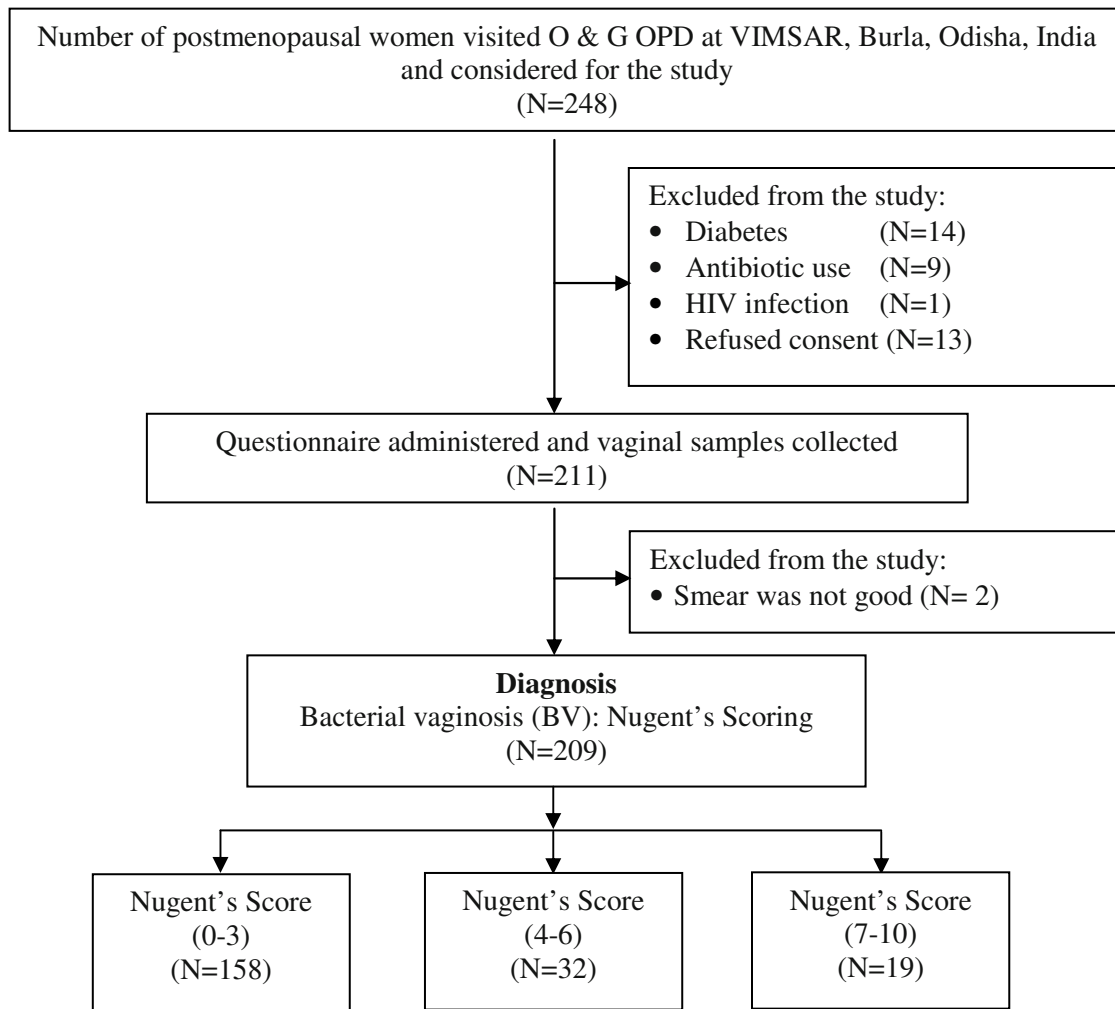
Diagnosis of BV: BV was diagnosed using Nugent's laboratory diagnostic criteria [15]. In brief; slides prepared from the vaginal swabs were stained with Gram's stain and examined for specific bacterial morphotypes [15]. A Nugent score (NS) between 0-10 was generated using the Nugent criteria. A NS of 0 to 3 was interpreted as normal or negative for BV, while a score of 4 to 10 was considered as intermediate/abnormal for BV or positive for BV.

Statistical analysis: All the generated data was entered in a Microsoft excel sheet for window. Data were presented in number followed by percentage. Pearson's Chi square test was performed for comparison of categorical data among the groups, A P value of < 0.05 was considered for statistical significant. All the statistical analysis was performed by using Stata 11.0 (StataCorp, Stata Statistical Software: Release 11. 2011, StataCorp LP: College Station, TX). The study was approved by Institutional Ethical Committee of Veer Surendra Sai Institute of Medical Sciences and Research (VIMSAR), Burla, Odisha (IEC/IRB-14/16).

Results

During the study period, 248 postmenopausal women were considered for the study. Out of which, 209 women were finally considered and recruited in this study. The detail recruitment of postmenopausal women in this study has been illustrated in Figure 1. The median age of women was 54 years with a range from 42 to 64 years of age.

Fig-1: Recruitment of postmenopausal women for the study

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│ Number of postmenopausal women visited O & G OPD at VIMSAR,       │
│ Burla, Odisha, India and considered for the study                 │
│                         (N=248)                                   │
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                                  │──────────────┐
                                  │    ┌──────────────────────────────────┐
                                  │    │ Excluded from the study:          │
                                  │    │ • Diabetes        (N=14)          │
                                  │    │ • Antibiotic use  (N=9)           │
                                  │    │ • HIV infection   (N=1)           │
                                  │    │ • Refused consent (N=13)          │
                                  │    └──────────────────────────────────┘
                                  ▼
┌─────────────────────────────────────────────────────────────────┐
│ Questionnaire administered and vaginal samples collected          │
│                         (N=211)                                   │
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                                  │    ┌──────────────────────────────────┐
                                  │    │ Excluded from the study:          │
                                  │    │ • Smear was not good (N= 2)       │
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                                  ▼
┌─────────────────────────────────────────────────────────────────┐
│                         Diagnosis                                 │
│           Bacterial vaginosis (BV): Nugent's Scoring              │
│                         (N=209)                                   │
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        ▼                         ▼                         ▼
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│ Nugent's Score  │     │ Nugent's Score  │     │ Nugent's Score  │
│     (0-3)       │     │     (4-6)       │     │     (7-10)      │
│    (N=158)      │     │    (N=32)       │     │    (N=19)       │
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On diagnosis, the vaginal pH analysis showed 92 (44.02%) women with a vaginal pH of < 4.5 and rest 117 (55.98%) with a vaginal pH of ≥ 4.5. A NS of 0-3 was found in 158 (75.60%) women, a score of 4-6 in 32 (15.31%) women and a score of 7-10 in 19 (9.09%) women. As per the diagnostic criteria, the overall prevalence of BV was 24.4% in the recruited postmenopausal women. The socio-demographic features of postmenopausal women recruited in the study according to with and without BV have been shown in Table-1.

The prevalence of BV was found to be associated with age, education and number of people lives in house. BV was significantly high (56.86%) in women more than 55 years of age compared to women with ≤ 55 years of age (P=0.018). Number of women with no formal education was significantly high (P=0.016) in women with BV (37.25%) compared to those without BV (20.25%). Women who staying together with ≥ 6 persons in the family had higher prevalence of BV (58.82%) compared to 27.2% of women without BV (P<0.0001). Other features like marital status, years of marriage, religion, caste, occupation, monthly income and residence (rural/urban) were comparable in women with and without BV.

Variables	With Bacterial Vaginosis 51 (24.4%)	Without Bacterial Vaginosis 158 (75.6%)	*P* value
Age (%)			
≤55 years	22 (43.14)	98 (62.03)	**0.018**
>55 years	29 (56.86)	60 (37.97)	
Marital status (%)			
Married	49 (96.08)	146(92.41)	0.362
Divorced/separated	2(3.92)	12(7.59)	
How many yrs have you been married			
<20 years	11 (21.57)	33 (20.89)	0.917
>20 years	40 (78.43)	125 (79.11)	
Religion			
Hindu	47 (92.16)	145 (91.77)	0.918
Muslim	2 (3.92)	5(3.16)	
Christian	2 (3.92)	8(5.06)	
Caste/Tribe			
Scheduled caste (SC)	11(22.45)	39(26.00)	
Scheduled tribe (ST)	15(30.61)	42(28.00)	
Other backward caste (OBC)	16(32.65)	48(32.00)	0.964
General	7(14.29)	21(14.00)	
Education			
No formal education	19(37.25)	32 (20.25)	
5th – 10th grade	23(45.10)	71(44.94)	**0.016**
12th grade or higher	9(17.65)	55(34.81)	
Occupation			
Employed	4 (7.84)	14 (8.86)	
Self-employed	12 (23.53)	36 (22.78)	0.972
Housewife	35 (68.63)	108 (68.35)	
People live in house			
1-2 individuals	2(3.92)	17 (10.76)	
3-5 individuals	19 (37.25)	98(62.03)	**0.001**
>6 individuals	30 (58.82)	43 (27.22)	
Monthly Income			
< 5,000	20 (39.22)	43 (27.22)	
5,000-10,000	13 (25.49)	55 (34.81)	0.229
>10,000	18 (35.29)	60 (37.97)	
Where Live			
Housing colony	10 (19.61)	28 (17.72)	
Urban slum	10 (19.61)	30 (18.99)	0.941
Rural/village	31 (60.78)	100 (63.29)	

Table-1: Association of various socio-demographic features with prevalence of BV in postmenopausal women. Data are expressed in Number (%) of women

Abnormal vaginal discharge was presented by 64.71% of women with BV which was significantly high (P=0.001) compared to 38.61% of women without BV. Similar observation has also been noticed in feeling of itching or burning of genitalia (64.71% Vs 44.30%) (P=0.011). Lower back pain was found in 52.94% of women with BV compared to 27.85% of women without BV (P=0.001). The comparisons on association of clinical symptoms in postmenopausal women with and without BV have been illustrated in Table-2.

Table-2: Association of various clinical symptoms with prevalence of BV in postmenopausal women. Data are expressed in Number (%) of women			
Clinical symptoms	**With Bacterial Vaginosis 51 (24.4%)**	**Without Bacterial Vaginosis 158 (75.6%)**	*p* value
Abnormal Vaginal Discharge			
No	18(35.29)	97(61.39)	**0.001**
Yes	33(64.71)	61(38.61)	
Burning/ itching in genitalia			
No	18 (35.29)	88 (55.70)	**0.011**
Yes	33 (64.71)	70 (44.30)	
Burning/itching during urination			
No	20 (39.22)	79 (50.00)	0.180
Yes	31 (60.78)	79 (50.00)	
Strawberry cervix			
No	21 (41.18)	99 (62.66)	**0.007**
Yes	30 (58.82)	59 (37.34)	
Genital sores			
No	49 (96.08)	151 (95.57)	0.876
Yes	2 (3.92)	7 (4.43)	
Lower back pain			
No	24 (47.06)	114 (72.15)	**0.001**
Yes	27 (52.94)	44 (27.85)	

Discussion

During the study period, 209 postmenopausal women were included in this study. The prevalence of BV in this study was found to be 24.40%. Similar observation has also been reported in women (Wave-1) recruited under National Social Life, Health and Aging Project (NSHAP) in United State and in women attending to a menopause clinic in UK [10,16]. In contrast, many studies have reported low prevalence of BV in postmenopausal women [7-8, 17]. These differences in the prevalence of BV in postmenopausal women may be due to the methods of diagnosis, hormonal replacement therapy, socio-demographic features etc. We have used Nugent's scoring system for the diagnosis of

BV and considered the women positive for BV who had a Nugent's score of more or equal to 4. Many studies have diagnosed BV by using Nugent's scoring system in postmenopausal women [6-7, 10, 16-18]. However, many authors have suggested use of Nugent's score for the diagnosis of BV is only validated in pregnant and reproductive age women, not for menopausal women [19-21].

In postmenopausal women, the vaginal pH is usually found to be increased compared to reproductive age women due to the hormonal changes. This high pH helps for growth of many anaerobic bacteria and hence occurrence of BV. Hormonal replacement therapy in postmenopausal women showed decrease in

the vaginal pH as well as reduction in the complications related to menopause. Many studied have reported that along with the decreased in vaginal pH level, there was an increase in the *Lactobacilli* population and hence reduced the chance of occurrence of BV after hormonal replacement therapy in postmenopausal women [22-24]. Although some of the women in this study have undergone hormone replacement therapy, we have not analyzed because the detail of therapy is uncertain in these women owing to their lack of knowledge and awareness for menopausal related complications and hormonal therapy.

Women with BV had been found to be presented with various clinical symptoms such as abnormal vaginal discharge, burning and itching of genitalia, strawberry cervix and back pain. None of the previous studies have analyzed the association of BV with clinical presentation of the postmenopausal women. However, in the reproductive age women abnormal vaginal discharge and burning, and itching of genitalia was found to be the most common problems associated with BV [25-27]. The association of various clinical symptoms with BV in this study may be due to others conditions like vulvovaginal candidiasis and/or infections of *Trichomonas vaginali* which were found to be associated with various clinical symptoms.

The prevalence of BV in postmenopausal women was found to be associated with various socio-demographic features. Women with age of >55 years (P=0.018), low educational level (P=0.016) and number of individuals living in the house (6 or more) (P<0.0001) was found to be significantly associated with occurrence of BV. Postmenopausal women recruited under NSHAP in United State, the prevalence of BV was found to be higher in older age women; however the authors have reported a higher age range (75-85 years age) compared to our study [10].

The high prevalence of BV in women with low educational level signified their lack of knowledge about proper sanitation, use of drugs and others behaviors pattern. Again the higher number of individuals living in a house may also impact the hygiene practices due to use of common toilet facilities and poor sanitation access. Previous studies have reported association of others factors such as sexual behaviors and use of probiotics, which have found to be influence the vaginal micro biome in postmenopausal women [8,16,28-29].

There is a limitation in this study. We have not analyzed the association of hormonal replacement therapy in our cases which has been found to be associated with prevalence of BV in postmenopausal women in previous studies.

Conclusion

This is the first report to elucidate the prevalence of BV in Indian postmenopausal women. Prevalence of BV was found to be high in symptomatic postmenopausal women in our study. Various socio-demographic features like age, education, marital status and number of family members were found to be associated with the prevalence of BV. Inclusion of more number of women with strict consideration of factors like hormonal replacement therapy will give a better conclusive result to this analysis.

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Conflicts of interest: There are no conflicts of interest.

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