

Factors affecting the incident of bacterial vaginosis in pelvic organ prolaps patients using pessarium during 2016-2019 in the Department of Obstetry and Gynecology RSUD Dr. Soetomo Surabaya

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Factors Affecting the Incident of Bacterial Vaginosis in Pelvic Organ Prolaps Patients Using Pesarium during 2016-2019 in the Department Of Obstetry and Gynecology Rsud Dr. Soetomo Surabaya

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Abstract

Background: Pelvic organ prolapse (POP) is the reduction of one or more female pelvic organs (vagina, uterus, bladder, rectum) into the vagina. With increasing age, the prevalence of POP also increases. Apart from age, risk factors for POP are multifactorial, namely vaginal delivery, increased body mass index (BMI), and a history of previous hysterectomy. Most of the patients with POP are asymptomatic and do not require treatment, but if necessary, one non-surgical approach is to use pessaries. A pessary is a medical device that is inserted into the vagina to provide structural support for pelvic organ prolapse or as a method of drug administration. Pessary use has side effects, with the most common being vaginal discharge (33%), vaginal irritation / pain (2-3%) and vaginal bleeding. Bacterial vaginosis (BV) is a clinical syndrome that shows foul-smelling vaginal discharge and an increase in vaginal pH. Bacterial Vaginosis diagnosis was based on Nugent's clinical criteria. One of the risk factors for BV in patients with pelvic organ prolapse using pessaries is smoking. Researchers wanted to know the factors that play a role in the occurrence of BV in POP patients using pessaries.

Methods: Data were collected through medical records of patients with pelvic organ prolapse using pessaries for the period 2016-2019 in the Department of Obstetrics and Gynecology, Dr. Soetomo Surabaya who met the inclusion and exclusion criteria, then performed a multivariate statistical test analysis.

Results: There were 36 patients experiencing BV out of a total of 47 patients using pessaries in POP patients while 11 other patients did not experience BV out of a total of 47 patients using pessaries in POP patients. A statistical test was carried out and it was found that menopausal status and BMI had a significant effect on the risk of BV in POP patients ($p=0,001$ dan $p=0,004$). Meanwhile, smoking was found to have no significant effect on the incidence of BV in POP patients who used pessaries.

Conclusion: POP patients with high BMI have an increased risk of developing BV while menopausal duration ≥ 10 years, the risk of BV on pessary use will increase.

Keywords: Pelvic organ prolapse, bacterial vaginosis, BV, pessaries, smoking

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I. Introduction

Pelvic organ prolapse (POP) is the lowering of one or more of a woman's pelvic organs (vagina, uterus, bladder, rectum) into the vagina. With increasing age, the prevalence of POP also increases. Apart from age, risk factors for POP are multifactorial, namely vaginal delivery, increased body mass index (BMI), and a history of previous hysterectomy. Most of the patients with POP are asymptomatic and do not require treatment (Jo et al., 2019). However, the prevalence of symptomatic POP in the general population is quite large, namely 11.4% (4-12.2%) which has a negative impact on daily activities and reduces the quality of life. Apart from pelvic floor muscle training, the use of pessaries and reconstructive surgery are the options for managing POP. Surgery for POP patients is associated with a recurrence or reoperation rate of up to 30% after initial surgery, therefore conservative treatment such as pessaries is the main treatment option according to the American Urogynecologic Society (AUGS) (D Susanne, 2020; Jo et al., 2019).

The pessary is a medical device that is inserted into the vagina to provide structural support for pelvic organ prolapse or as a method of drug administration (Devi & Jalem, 2017). In the Netherlands 98% of physicians report the use of pessaries in POP management and 77% of gynecologists report using pessaries as a first-line therapy option (D Susanne, 2020). Correct placement of pessaries has a success rate of 65-86% and will relieve symptoms in 65-89% of patients (Coelho et al., 2017). Compared to surgery, the advantages of using a pessary are a lower complication rate, an indication of immediate effectiveness, and a lower short-term cost. The indications for starting pessary therapy are reducing POP symptoms, preventing the progression of prolapse and avoiding surgery (D Susanne 2020).

However, using pessaries also has its downsides. The most common side effects of pessaries were vaginal discharge (33%), vaginal irritation / pain (2-3%) and vaginal bleeding (6-46%). Although there are rarely more serious side effects from pessary use such as fistulas, hydronephrosis, urosepsis (D Susanne 2020). The most frequent complication associated with pessary use is vaginal discharge which occurs in 56% of users (Coelho et al., 2017). According to the research of Sarah Collins et al. women who used pessaries had complaints of vaginal discharge compared to the control group (30.0% versus 2.1%, $p < 0.001$) in the first 2 weeks of using pessaries. Many studies have reported the effects of pessaries on the vaginal microenvironment (Devi & Jalem, 2017). Bacterial vaginosis (BV) was diagnosed in 32% of pessary users compared with 10% of the control group within the first 6 months of use. The presence of foreign bodies and changes in the ecosystem in the vagina can trigger an inflammatory response and support the presence of other microbes (Devi & Jalem, 2017).

Bacterial vaginosis (BV) is a clinical syndrome that shows foul-smelling vaginal discharge and an increase in vaginal pH. Bacterial Vaginosis diagnosis was based on Nugent's clinical criteria (Sha et al., 2005). The normal vaginal flora, which consists of hydrogen peroxide-producing lactobacilli, was replaced by *Gardnerella vaginalis*, *Mycoplasma hominis*, *Mobilocus* species, and anaerobic gram-negative stem bacteria. Bacterial vaginosis is associated with preterm labor, chorioamnionitis, post-abortion infections, and pelvic inflammatory disease (Sha et al., 2005). From several studies conducted by Amaral et al., Fether et al., And Yudin et al., Found that age, race, smoking, vaginal douching, IUD and sexual behavior are risk factors for bacterial vaginosis (Yudin et al., 2008). One of the risk factors for BV in patients with pelvic organ prolapse using pessaries is smoking. The combination of pessary use and smoking increased the risk of bacterial vaginosis by 9.6 times ($p = 0.0013$ OR = 3.78 95% CI = 2.05-8.25) (Alnaif & Drutz, 2000). Research conducted by Faria Toma et al found that the incidence of BV after pessary placement in post-menopause with pelvic organ prolapse increased significantly ($p = 0.00$) (Faria Toma, 2017).

Comorbid disease is also a risk factor for BV in patients with pelvic organ prolapse using pessaries. In patients with comorbid diseases, cellular and congenital immunity disorders occur, namely lower production of cytokines and chemokines (Murphy & Mitchell, 2016). Body mass index greater than equal to 30 kg / m² (obesity) can cause hormonal disorders, metabolism, eating habits, gut microbiota, and / or immunity which can affect the composition of the vaginal microbiota of BV in patients with pelvic organ prolapse using pessaries (Brookheart et al., 2019).

Because there is still little literature that examines the risk factors that cause BV in patients with pelvic organ prolapse using pessaries and in order to prevent the incidence of BV in patients with pelvic organ prolapse using pessaries, further studies are needed to determine the risk factors that cause BV in patients with organ prolapse. pelvis using a pessary.

II. Methods :

Data were collected through medical records of patients with pelvic organ prolapse using pessaries for the period 2016-2019 in the Department of Obstetrics and Gynecology, Dr. Soetomo Surabaya who met the inclusion and exclusion criteria. Medical record of 159 pelvic organ prolapse patients are retrieved. The exclusion we used are incomplete medical record, patient with no history of using pessarium, patient with history of using IUD and Douchine habitual. We separate patient into two groups namely Swab (+) and Swab (-) group and compared each of the risk factor that may applied. We performed a multivariate statistical test analysis from the data collected above.

III. Result

Based on the characteristics of BV and non-BV patients, based on the degree of Pelvic Organ prolapse using pessaries, it can be seen that in the group suffering from BV the most were samples with grade 4 Pelvic Organ prolapse, namely 15 cases (41.6), and the second order was grade 3 as many as 11 cases (30.6), followed by grade 2 in 8 cases (22.2) and degree 1 by 2 cases (5.6).

Furthermore, the statistical test results showed a significant value of 0.040 ($p < 0.05$), which means that there was a significant difference in the degree of POP in the group that experienced BV and the group that did not experience BV who used pessaries.

Table 1. The degree of POP in the group of patients with BV and those who did not have BV

Degree of POP	Total (n)	Percentage (%)	BV -	BV +	p
1	4	8.5%	2 (18.2)	2 (5.6)	0.040*
2	13	27.7%	5 (45.4)	8 (22.2)	
3	13	27.7%	2 (18.2)	11 (30.6)	
4	17	36.2%	2 (18.2)	15 (41.6)	
Total	47	100.0%	11 (100)	36 (100)	

*Kruskal wallis test

Table 2 Risk factors for POP patients with BV and no BV

Risk Factor	BV (-)	BV (+)	p
Age			
20-39 years old	0 (0)	2 (5.5)	0.535*
40-59 years old	5 (45.5)	18 (50.0)	
60-79 years old	6 (54.5)	15 (41.7)	
≥ 80 years old	0 (0)	1 (2.8)	
Menopausal Status			
Menopause	5 (45.5)	34 (94.4)	0.001^
No menopause	6 (54.5)	2 (5.5)	
Menopause			0.000*
< 5 years	2 (18.2)	10 (27.8)	0.004*
5-<10 years	0 (0)	5 (13.9)	
>=10 years	3 (27.3)	19 (52.7)	
BMI			
normal	7 (63.6)	7 (19.4)	0.004*
overweight	1 (9.1)	2 (5.6)	
Obesity class 1	3 (27.3)	25 (69.4)	
Obesity class 2	0 (0)	2 (5.6)	
Smoking			1.0*
< 1 Pack/day	3 (27.3)	6 (16.7)	0.725^
1 Pack/day	0 (0)	3 (8.3)	
>1 Pack/day	0 (0)	0 (0)	
No smoking	8 (72.7)	27 (75.0)	
Comorbidity			
1 comorbid	3 (27.3)	13 (36.1)	0.725^
comorbid	8 (72.7)	23 (63.9)	

*kruskall Wallis test

^Fisher test

#Kolmogorov-Smirnov test

Based on the age factor, it is known that a total of 36 patients had BV, the most 18 cases (50.0) in the 40-59 years age group had BV, and of the 11 patients who did not have BV, the most 6 cases (54.5) were in the 60-79 age group, year.

Based on the classification of menopausal status, it is known that of the 36 patients who experienced BV, the most 34 cases (94.4) in the menopausal group experienced BV, and of the 11 patients who did not experience BV, the most 6 cases (54.5) were in the pre-menopausal group.

Based on the classification of the duration of menopause, it is known that of the 36 patients who experienced BV, the most were 19 cases (52.7) who had experienced menopause >= 10 years, and of the 11 patients who did not experience BV, the most had also experienced menopause >= 10 years, namely 3 case (27.3) Furthermore, the statistical test results show a significance value of 0.000 (p <0.05), which means that there is a significant difference in the incidence of BV in the menopausal group and the postmenopausal group.

For the classification of BMI, it is known that in the group that experienced BV, there were more patients with BMI classified as obese class 1, namely 25 cases (69.4), and in the group that did not experience BV, there were more patients with BMI classified as normal, namely 7 cases. (63.6). From the results of the statistical test showed a significance value of 0.004 (p <0.05), which means that there was a significant difference in the BMI of patients in the group experiencing BV and the group without BV.

For a history of smoking, it is known that in the group that experienced BV the number of patients who did not smoke was 27 patients (75.0), and in the group that did not experience BV was more found in patients who did not smoke as many as 8 patients (72.7). The statistical test results showed an insignificant value of 1.00 (p > 0.05), which means that the group that experienced BV and the group that did not experience BV had a sample size of mothers with a smoking history that was not significantly different.

For comorbid diseases, it is known that in the group that experienced BV the number was higher in the group without comorbid as many as 23 cases (63.9), and in the group that did not experience BV the number of samples was also in the group without comorbid as many as 8 cases (72.7) . The statistical test results showed an

insignificant value of 0.725 ($p > 0.05$), which means that the group that experienced BV and the group that did not experience BV had the number of samples of mothers with the number of comorbid diseases that were not significantly different.

Based on data from patients with pelvic organ prolapse using pessaries for the period 2016-2019, information was obtained with the following details.

Table 3. Incidence of BV after 3, 6 and 9 months of pesarium separation

	3 Months	6 Months	9 Months
BV (-)	11 (23.4)	23 (48.9)	15 (31.9)
BV (+)	36 (76.6)	23 (48.9)	8 (17.0)
No	-	1 (2.2)	24 (51.1)
P score	< 0.000	< 0.000	< 0.000

Based on the table above, it shows that after 3 months of using pessaries, it is known that of the 47 patients there were 36 cases (76.6) who had BV, 11 cases (23.4) did not experience BV. Furthermore, the statistical test results show a significance value of < 0.000 ($p < 0.05$), which means that there is a significant relationship between the incidence of BV and the placement of pessaries for 3 months.

After 6 months of using pessaries, it was known that of the 47 patients, 23 patients (48.9) had BV, 23 patients (48.9) did not experience BV, and 1 patient (2.2) had no data. Furthermore, the statistical test results show a significance value of < 0.000 ($p < 0.05$), which means that there is a significant relationship between the incidence of BV and pessary insertion for 6 months.

Then after 9 months of using pessaries, it was known that out of 47 patients there were 8 patients (17.0) who had BV, 15 patients (31.9) did not experience BV, and 24 other patients (51.1) had no data. Furthermore, the statistical test results show a significance value of < 0.000 ($p < 0.05$), which means that there is a significant relationship between the incidence of BV and pessary insertion for 9 months.

Furthermore, to determine the determinant factors that affect the incidence of BV due to the use of pessaries, a logistic regression test was carried out with the following results.

Table 4. Multivariate Logistic Regression Analysis of BV Risk Factors

Variable	P score	OR	95% CI	
			min	max
Menopause	0.043	2.038	1.023	4.060
BMI	0.039	1.229	1.011	1.495

Significant if $p < 0.05$

Based on the results of statistical tests for the determinant factors that affect the incidence of BV due to the use of pessaries above, it shows that the menopause and BMI variables have a significance value of 0.043, and 0.039 which is smaller than 0.05, so it can be concluded that menopause and BMI have a significant effect on the incidence. BV due to pessary use.

The Odds Ratio (OR) value for menopause is 2,038, meaning that the sample of mothers in the case group, namely those with BV, has a probability of 2,038 times (95% probability CI range between 1,023 to 4,060 times) the risk of BV in patients with menopausal status who $> = 10$ years, compared with the group that did not experience BV.

The BMI factor has an Odds Ratio (OR) value of 1.229, meaning that the sample of mothers in the case group, namely those experiencing BV, has a probability of 1,229 times (95% probability CI range between 1,011 to 1,495 times) the risk of BV in patients who have a BMI that is higher than BMI in the control group without BV.

IV. Discussion

In this study, in the sample using pessaries, it was known that from 47 samples there were 36 cases with BV, and 11 other samples did not experience BV. Meanwhile, in the sample that did not use pessaries, it was found that from 57 samples there were 16 cases that experienced BV. Furthermore, the test results showed a significance value of 0.000 ($p < 0.05$), which means that there was a significant difference in the incidence of BV in the group that did not use pessaries and the group that used pessaries, because the number of samples with the incidence of BV in the two groups was different. quite a lot, so that statistically the difference is really real (meaningful). In other words, the pessary-using group tended to have more samples who experienced BV, while the non-pessary group tended to have more samples who did not experience BV.

The pessary itself is a foreign object that can trigger an inflammatory response. Inflammatory reactions due to foreign bodies (pessaries) in subjects who have risk factors, namely menopausal status, increased body mass index, smoking habits, and the presence of comorbid diseases.

In this study, for menopausal status, it was known that in the group suffering from BV the most were patients who had menopause > 10 years, as many as 19 patients (52.7). The statistical test results showed a significance value of 0.000 ($p < 0.05$), which means that there is a significant difference in the incidence of BV based on menopausal status. Based on the results of statistical tests for the determinant factors that influence the incidence of BV due to the use of pessaries above, it shows that the menopausal status variable has a significance value of 0.001 which is smaller than 0.05, so it can be concluded that menopausal status has a significant effect on the incidence of BV due to pessary use. The menopause status factor has an Odds Ratio (OR) value of 2.038, meaning that patients in the case group, namely those experiencing BV, have a probability of 2,038 times (95% probability CI range between 1,023 to 4,060 times) has a higher menopausal status than menopausal status in the control group that is not experiencing BV. These results are in accordance with the research conducted by Faria Toma et al. It was found that the incidence of BV after pessary insertion in postmenopause with pelvic organ prolapse increased significantly ($p = 0.00$) (Faria Toma, 2017). In women over 60 years of age and who have menopause, the hormone estrogen decreases as a result of decreased vaginal glycogen stores so that the mobilization of glucose and the production of lactic acid in the vaginal epithelium decreases. This condition causes vaginal pH to increase and leads to the growth of anaerobic organisms (Coelho et al., 2017; Collins et al., 2015; Devi & Jalem, 2017)

Functionally, menopause begins when the number of primordial follicles (which continue to decrease from birth) reaches its lowest point. Plasma estrogen levels drop from about 129 ng / L in the reproductive year to about 18 ng / L after menopause, affecting the vagina. (Farage et al., 2010). Postmenopause is a non-reproductive condition characterized by hormonal changes, more specifically, decreased levels of ovarian hormones, estrogen and progesterone. Without this hormone, the vaginal mucosa thins and begins to stop growing, becoming smaller and less elastic. Functionally, the vagina produces less secretion, less lubrication and is more prone to minor tearing during sexual intercourse or masturbation which can lead to dyspareunia (Hoffmann, J. N. et al. 2014). When estrogen levels fall, the vaginal epithelium, which contains estrogen-alpha receptors, will cause vaginal epithelial atrophy (Farage et al., 2010). Vaginal atrophy affects up to 47% of postmenopausal women, but symptoms often go unreported by patients because of embarrassment about discussing "personal" symptoms or the belief that they are a normal part of aging. Thus, only about a quarter of women who experience symptoms of vaginal atrophy, such as burning, itching, abnormal vaginal discharge, and discomfort with urination seek medical care. The postmenopausal vaginal environment, including vaginal atrophy, can also cause a shift in microbial colonization that can lead to vaginal infections in older women. Bacterial vaginosis (BV) is the most common vaginal infection in women of reproductive age and is caused by a shift in the vaginal flora from aerobic to the predominantly pathogenic anaerobic bacteria. (Hoffmann, J. N. et al. 2014)

For the classification of BMI, it is known that in the group suffering from BV the most are in the group with BMI obesity class 1, namely 25 patients (69.4), and patients in the group who do not suffer from BV are more in patients with normal BMI, namely as many as 7 patients (63.6). Based on the results of statistical tests for the determinant factors that influence the incidence of BV due to the use of pessaries above, it shows that the BMI variable has a significance value of 0.004 which is smaller than 0.05, so it can be concluded that BMI has a significant effect on the incidence of BV due to the use of pessaries. The BMI factor has an Odds Ratio (OR) value of 1.229, meaning that patients in the case group, namely those experiencing BV, have a probability of 1,229 times (95% CI probability range between 1,011 to 1,495 times) has a BMI higher than BMI in the control group. that is, those who do not experience BV. Some degree of POP occurs in 65% of women over 65 years but far fewer (10%) report bothersome symptoms (a bulging sensation). Parity, vaginal delivery, age, and BMI are risk factors for POP based on a recent systemic review. (Takacs, P., Kozma, B. and Larson, K. 2019).

With regard to smoking, the statistical test results in this study showed an insignificant value of 1.00 ($p > 0.05$), which means that the group suffering from BV and the group that did not suffer from BV had no significant difference in the number of smoking patients. This study is not in accordance with the study of Smart et al., 2004, namely women with BV who smoked and consumed higher amounts of alcohol > 140 g per week showed significant results (13% v 10%, OR = 1.4, $p = 0.04$). In addition, this study shows that the number of cigarettes consumed per day has an effect on the incidence of BV.

For comorbid diseases, it is known that in the group that experienced BV the number was higher in the group without comorbid as many as 23 cases (63.9), and in the group that did not experience BV the number of samples was also in the group without comorbid as many as 8 cases (72.7). The statistical test results showed an insignificant value of 0.725 ($p > 0.05$), which means that the group that experienced BV and the group that did not experience BV had the number of samples of mothers with the number of comorbid diseases that were not significantly different.

V. Conclusion

There were 36 patients experiencing BV out of a total of 47 patients who used pessaries in Pelvic Organ prolapse patients. There were 11 other patients who did not experience BV out of a total of 47 patients who used pessaries in Pelvic Organ prolapse patients. There was a significant difference in the incidence of BV based on menopausal status, where the incidence of BV in patients using pessaries was found in patients who had menopause > 10 years, as many as 19 patients (52.7) with a significance value of 0.000 ($p < 0.05$). There was a significant effect of BMI on the incidence of BV due to pessary use, in the group with BMI obese class 1, there were 25 patients (69.4), with a significance value of 0.004 ($p < 0.05$).

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