

Original Research Article


# The effect of Pessaries on Vaginal Micro environment

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## Abstract

**Background:** Pessary is a medical device inserted into the vagina, either to provide structural support or as a method of delivering medication. For the treatment of urinary incontinence, pelvic organ prolapse, pessaries have been utilized.

**Aim:** The aim of the study was to evaluate the differences in vaginal discharge between postmenopausal women who wear pessaries and those who do not to explain pessary related, bacterial vaginosis vaginal discharge by microscopy, gram staining.

**Materials and Methods:** 150 women were selected for the study and the study was conducted at Government hospital Nizamabad and CKM hospital, Warangal. 75 Women were post-menopausal who had worn Pessaries for at least 4months and were in group A. 75 Women didn't wear Pessaries and were presenting for pessary fitting. Women who were postmenopausal, women who had worn pessaries for atleast 4 months or had never worn pessary and were presenting for pessary fitting were included.

**Results:** Group A was older and had been for a longer time menopausal when compared to Group B. Years since menopause was higher in group A when compared to group B. Women in group A were more bothered by discharge when compared to group B. Women in group A were more likely to meet amsel's and nugen't's criteria for bacterial vaginosis. In group A, the WBC's were greater than 10 per hpf when compared to group B by microscopy. Clue cells were higher in group A when compared to group B. pH also was higher in group A when compared to group B.

**Conclusion:** Bothersome vaginal discharge may be due to vaginal inflammatory process and it develops early and is pessary related.

## **Key words**

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Effect, Pessaries, Vagnial Microenvironment.

## **Introduction**

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Pessary is a medical device inserted into the vagina, either to provide structural support or as a method of delivering medication. For the treatment of urinary incontinence, pelvic organ prolapse, pessaries have been utilized. There is an assumption that increased vaginal discharge could represent a vaginal infection and which is off-putting for patients and their physicians alike [1, 2]. A pessary is a device placed into the vagina to support the prolapsing vaginal walls or to provide urinary continence. Pessaries have the distinct advantage of being minimally invasive, and they provide immediate relief of symptoms. Although in the past, pessaries were reserved for the frail and elderly, they are also an excellent alternative for symptomatic women who have not finished child-bearing and for those who choose a non-surgical intervention or who wish symptomatic relief while awaiting surgery [3,4]. Pessaries are experiencing a resurgence in popularity and are an option for the treatment of prolapse and incontinence for women in any age group. Pessaries are made of medical grade silicones, only the largest sizes are made of surgical steel with a covering of silicone. This makes it easy to insert and also decreases the odour and less allergic. Pessaries which are used for medical treatment can be classified as support pessaries or space occupying pessaries. This pessary therapy improves symptom i.e. 65-86% of pessary, 65-89% with prolapse and 47-94% with stress incontinence [5, 6]. The use of pessaries has many side effects which are complaints of vaginal discharge, foul odour. Compared with those who do not use pessaries, even less is known about the difference in microorganisms present in women who wear pessaries.

## **Materials and methods**

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150 women were selected for the study and the study was conducted at Government hospital Nizamabad and CKM hospital, Warangal. 75

Women were post-menopausal who had worn Pessaries for at least 4months and were in group A. 75 Women didn't wear Pessaries and were presenting for pessary fitting.

### **Inclusion criteria**

Women who were postmenopausal, Women who had worn pessaries for atleast 4 months or had never worn pessary and were presenting for pessary fitting.

### **Exclusion criteria**

Women who were pre or perimenopausal, who had cognitive deficits challenging participation. Women who had exogenous systemic or vaginal estrogen therapy, who had used pessary for 0-4 months, or performed self-maintenance of pessary. Antibiotic use systemically or through vaginal route.

In group A, the data collection was done once only. In group B, data collection was done at first visit, 2 weeks, 3 months and 6 months later. Subjects had to undergo a speculum examination with vaginal sample collection. In group B, in their first visit, this examination was done before pessary fitting or after the pessary was removed for cleaning. To avoid contamination of culture, the speculums were moistened with tap water before placement. Gram stain or microscopy specimens with water based lubricants. Specimens were placed in anaerobic transplant vials for culture i.e. aerobic or anaerobic and gram stain as soon as the swabs were placed in the vaginal vault. PH was measured using PH paper and a wet mount was prepared. Microscopy was done to calculate clue cells percentage and number of WBC's. Modified Amsel's criteria was used to check the characteristic vaginal discharge, vaginal fluid pH greater than 4.5; positive odour of amine, 20 % or greater prevalence of clue cells on microscopy indicated diagnosis of nonspecific vaginitis. Specimens of culture were gram stained and analysed for

bacterial vaginosis using nugen’s criteria. It is a sum of 3 subscores each of the subscore quantifies a different category of organism i.e. large gram positive rods, small gram negative rods and curved gram negative rods. Gram positive rods decrease the scoe and gram negative rods and curved gram negative rods increase the score. A score of 0-3 is normal, 4-6 intermediate and 7-10 consistent with bacterial vaginosis.

**Results**

Group A and Group B, each group consisted of 75 women.

**Table - 1** shows that Group A was older and had been for a longer time menopausal when

compared to Group B. Years since menopause was higher in group A when compared to group B. Women in group A were more bothered by discharge when compared to group B. Women in group A were more likely to meet amsel’s and nugen’s criteria for bacterial vaginosis. In group A, the WBC’s were greater than 10 per hpf when compared to group B by microscopy. Clue cells were higher in group A when compared to group B. pH also was higher in group A when compared to group B.

Comparison in group A: those with bothersome discharge and those without were as per **Table – 2**. Comparison of most prevalent organisms in both groups were as per **Table – 3**.

**Table – 1:** Demographic characteristics.

Characteristic	Group A	Group B	P value
Age (Mean±SD)	80.6±6.7	74.6±2.4	.005
Years since menopause(Mean±SD)	35±5.8	26.8±4.5	.004
Bothered by discharge n,%	30\75, 40%	10\74,13%	<.001
BV by Amsel’s criteria n,%	28\75, 37.33%	4\75, 5.3%	.05
BV by Nugent’s criteria n,%	36\74, 48.6%	12\75,16%	.03
WBC’s (≥10 per hpf), n,%	43\75, 57.3%	4\75, 5.3%	<0.01
Clue cells(Mean±SD)	15.8±38.1	2.8±6.1	.01
pH(Mean±SD)	6.7±3.0	6.2±2.7	.20

**Table – 2:** The comparison in group A: those with bothersome discharge and those without.

Variable	Bothered discharge	Not bothered	P value
BV by Amsel’s criteria n,%	8\30, 26.6%	0\45, 0%	.005
BV by Nugent’s criteria n,%	7\30, 23.3%	10\45,22.2%	.70

**Table – 3:** Comparison of most prevalent organisms in both groups.

Variable	Group A(n=75)		Group B(n=75)
Most common organisms	Not Bothered discharge (n=45)	bothered (n=30)	Corynebacterium sp(20)
	Corynebacterium sp (22)	Corynebacterium sp (10)	Streptococcus viridans(10)
	Streptococcus viridans(8)	Streptococcus viridans(7)	Lactobacillus sp(8)
	Lactobacillus sp(8)	Lactobacillus sp(5)	Staphylococcus(20)
	E coli(4)	E coli(4)	E coli(7)
Stsphylococcus(3)	Enterococcus sp(4)	Enterococcus sp(10)	

**Discussion**

Many studies have reported the effect of pessaries on the vaginal microenvironment. Sarah Collins,

et al. [7]; conducted a study whose objective was to evaluate the differences in vaginal culture, microscopy, and Gram stain between post-menopausal women who wear pessaries and

those who do not to explain pessary-related, bothersome vaginal discharge. Postmenopausal women not using exogenous estrogen who had either been wearing a pessary for at least 3 months or who were undergoing their first pessary fittings were approached for enrollment. Symptoms were assessed, and vaginal fluid was collected for culture, microscopy, and Gram stain. A cross-sectional analysis was performed, comparing the new and return pessary wearers. The new pessary users were also sampled at 2 weeks, 3 months, and 6 months after fitting. The results were that women who wore pessaries were more likely to be bothered by discharge (30.0% vs 2.1%,  $P < .001$ ). They were also more likely to show microscopic evidence of vaginal inflammation and vaginitis. Prospective data showed that these changes developed during the first 2 weeks of pessary use. Aerobic and anaerobic organisms were nearly identical in women with and without bothersome vaginal discharge in the cross-sectional analysis and at all time points in the prospective analysis. This study concluded that Pessary-related, bothersome vaginal discharge develops early and may be due to an inflammatory process in the vagina. Many providers recommend concurrent estrogen therapy with pessary use to limit complications; however, limited data exist to support this practice. We hypothesized that vaginal estrogen supplementation decreases incidence of pessary-related complications and discontinuation. Sybil G. Dessie, et al. [8]; performed a retrospective cohort study of women who underwent a pessary fitting from 1 January 2007 through 1 September 2013 at one institution; participants were identified by billing code and were eligible if they were post-menopausal and had at least 3 months of pessary use and 6 months of follow-up. All tests were two sided, and  $P$  values  $< 0.05$  were considered statistically significant. Data from 199 women were included; 134 used vaginal estrogen and 65 did not. Women who used vaginal estrogen had a longer median follow-up time (29.5 months) compared with women who did not (15.4 months) and were more likely to have at least one pessary check (98.5 % vs 86.2 %,  $P < 0.001$ ). Those in the estrogen group were less

likely to discontinue using their pessary (30.6 % vs 58.5 %,  $P < 0.001$ ) and less likely to develop increased vaginal discharge than women who did not [hazard ratio (HR) 0.31, 95 % confidence interval (CI) 0.17–0.58]. Vaginal estrogen was not protective against erosions (HR 0.93, 95 % CI 0.54–1.6) or vaginal bleeding (HR 0.78, 95 % CI 0.36–1.7). Women who used vaginal estrogen exhibited a higher incidence of continued pessary use and lower incidence of increased vaginal discharge than women who did not. Supriya Bulchandani, et al. [9]; conducted a study whose objective was that pelvic organ prolapse is often co-existent with atrophy of the genital tract in older women who tend to prefer vaginal pessaries for prolapse. Vaginal estrogen therapy is used by some along with a support pessary for prolapse with no robust evidence to back this practice. We aimed to evaluate differences in complications of support pessaries for vaginal prolapse in postmenopausal women, with and without vaginal estrogen use. This study prospectively assessed postmenopausal women attending the urogynaecology clinic for a pessary change. We asked them about the level of discomfort during pessary change (visual analogue scale for pain), discharge, bleeding and infection. Ethics approval was not required as this was a service evaluation project. Statistical analysis for relative risk was performed, including sub-group analysis for ‘ring pessary’ and ‘non-ring group’ (Shelf, Gellhorn, Shaatz). Results: Between July 2013 and December 2014, we assessed 120 postmenopausal women using support pessaries for prolapse. The mean age was 70 years; 45% of the patients used vaginal estrogen. There were no statistically significant differences in complications with or without vaginal estrogen use, although the trend was higher amongst non-users. The ‘non-ring’ sub-group not using vaginal estrogen had a higher risk of vaginal ulceration, bleeding and discharge. Postmenopausal women may have lesser complications when using vaginal estrogen with a support pessary for prolapse, particularly with pessaries other than the ring. An adequately powered randomised controlled trial is needed to assess conclusively whether vaginal estrogen enhances comfort and

reduces complications of support pessaries for prolapse. Alnaif B, et al. [10]; conducted a study whose purpose was to examine the association between pessary use, smoking and changes in the vaginal flora. Patients using pessaries were age matched with non-pessary using controls. All candidates examined were women attending the Mount Sinai Hospital, Toronto, for genitourinary problems. Vaginal cultures were routinely performed on all women attending the unit, irrespective of symptoms. Forty-four pessary users were age matched with 176 controls (4 controls per case). The mean age was 60.1 +/- 12.6 years, and 15% of these were premenopausal. The duration of pessary use ranged from 0.5 to 8 years (mean 3.3 +/- 1.7). Weight, parity, smoking status, diabetes mellitus, thyroid disease, UTI and postvoid residual urine volume were not significantly different between pessary users and controls. Bacterial vaginosis (BV) was noted in 32% of pessary users, versus 10% of controls. The relative risk of developing BV in pessary users was 3.3 (OR, 4.37; 95% CI, 2.15-9.32),  $P = 0.0002$ . Smoking independently affected the vaginal flora, increasing the relative risk of developing BV to 2.9 (OR, 3.78; 95% CI, 2.05-8.25),  $P = 0.0013$ . It was concluded that pessary use is a very effective and conservative method for the treatment of genital prolapse. However, we found that the presence of a foreign body was associated with changes in the vaginal flora, thereby increasing the odds of developing bacterial vaginosis to 4.37; this was further compounded by smoking.

## Conclusion

Bothersome vaginal discharge may be due to vaginal inflammatory process and it develops early and is pessary related.

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