Can the Pessary Use Modify the Vaginal Microbiological Flora? A Cross-sectional Study

O uso de pessário vaginal pode alterar a flora microbiológica? Um estudo transversal

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Abstract

Introduction Vaginal pessary is used as a conservative treatment for pelvic organ prolapse (POP). Some studies have shown that common complaints of its use may include vaginal discomfort and increased vaginal discharge. Scant information is available about the microflora status after using this device.

Objective To determine if the usage of vaginal pessary can interfere with the vaginal environment.

Methods A cross-sectional study was performed from March of 2014 to July of 2015 including 90 women with POP. The study group was composed of 45 women users of vaginal pessary and 45 nom-users. All enrolled women answered a standardized questionnaire and were subjected to a gynecological exam to collect vaginal samples for microbiological evaluation under optic microscopy. Clinical and microbiological data were compared between study and control groups.

Results Vaginal discharge was confirmed in 84% of the study group versus 62.2% in the control group ($p < 0.01$); itching was reported in 20 and 2.2%, respectively ($p < .05$); genital ulcers were only found in the pessary group (20%). There was no difference with regard to the type of vaginal flora. Bacterial vaginosis was prevalent in the study group (31.1% study group versus 22.2% control group), ($p = .34$).

Conclusion Women using vaginal pessaries for POP treatment presented more vaginal discharge, itching and genital ulcers than non-users.

Keywords
- vaginal pessary
- itching
- pelvic organ prolapse
- vaginal flora
- cross-sectional study

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Resumo

Introdução O pessário vaginal é utilizado como tratamento conservador para o prolapso de órgãos pélvicos (POP). Alguns estudos demonstraram que as queixas mais comuns do seu uso são o desconforto vaginal e um aumento do fluxo vaginal. As informações são escassas a respeito do que ocorre com a microflora vaginal após o uso do pessário.

Objetivo Determinar se o uso do pessário pode interferir com o ambiente vaginal.

Métodos Um estudo transversal realizado de março de 2014 a julho de 2015 com 90 mulheres com POP; metade delas usaram pessário e a outra metade permaneceu como grupo controle. Todas preencheram um questionário e realizaram exame ginecológico para coleta de amostras vaginais para análise microbiológica. Dados clínicos e microbiológicos foram comparados entre os grupos de estudo e de controle.

Resultados O fluxo vaginal foi confirmado em 84% das mulheres do grupo de estudo versus 62,2% do grupo de controle ($p < 0,01$); prurido foi encontrado em 20 e 2,2%, respectivamente ($p < 0,05$). As úlceras genitais foram somente encontradas no grupo pessário (20%). Não houve diferenças com relação ao tipo de flora vaginal. A vaginose bacteriana fora encontrada em 31,1% das mulheres do grupo de estudo versus 22,2% do grupo de controle ($p = 0,34$).

Conclusão Mulheres usando pessários vaginais para tratamento do POP apresentaram maior fluxo vaginal, prurido e úlcera genital do que as não usuárias do dispositivo.

Palavras-chave

- pessário vaginal
- prurido
- prolapso genital
- flora vaginal
- estudo transversal

Introduction

Pelvic organ prolapse (POP) is a growing condition in women worldwide. Conservative treatment of this disease is multidisciplinary and includes several options; one of them is the vaginal pessary. The conservative approach with the use of pessaries is a viable treatment and results in a better quality of life for women with POP.[1–3] Vaginal therapeutic pessaries are rubber medical rings that work with a diaphragm to supports the uterus, vagina, bladder and rectum. Studies show that the success rate in placing the therapeutic pessary is 65–86%, with relief of symptoms in 65–89% of the patients.[4,5] The pessary is a good alternative treatment for POP in women who do not want to undergo surgery, or even those awaiting surgery in larger medical institutions with a high influx of patients. Moreover, studies have shown that it improves the quality of life and sexual function, and decreases vaginal symptoms.[6–8] There are few contraindications to pessary use.[1,3] It is a minimally invasive device and presents low risk, but it can show some complications.[6,8] For instance, vaginal discharge is the primary adverse effect of women using pessary.[6,8]

Currently, there are scant data on the use of this device and the possible symptoms associated with its use. Recent studies show that the most common complaints are genital discomfort, increase in vaginal discharge and foul-smelling odor.[5,6] The incidence of these complaints is 13.5–17.3%.[5] Little is known about the impact of the pessary use in the vaginal flora of these women. The presence of a foreign body inside the vagina may favor the existence of different microorganisms.[5,6] A study that assessed vaginal changes in women using pessary when compared with a control group found that 32% of pessary users developed bacterial vaginosis (BV) compared with 10% of the control group in the first 6 months of treatment.[7] Also, it is not yet comprehensible what triggers the process of change in the vaginal flora of women who use pessaries; assumptions are made about a possible, inflammatory reaction.[5] Given the necessity of better advising patients, it is essential to increase the amount of scientific data about therapeutic pessaries to guide health providers concerning the benefits and possible adverse effects that may accompany its use. A better understanding of this aspect would directly benefit women with POP who are seeking conservative treatment. The aim of this study was to evaluate genital complaints and microbiological findings in women with POP who use pessary.

Methods

Study Design and Inclusion/Exclusion Criteria

This is a cross-sectional study performed at the Gynecological Surgery Outpatient Clinic of the Faculdade de Medicina da Universidade Estadual de Campinas (UNICAMP) that included 90 women with POP from March of 2014 to July of 2015. This study was approved by our Institutional Review Board (protocol number 053/2013). Women with genital prolapse with pelvic organ prolapse quantification (POP-Q) stage 3 or 4[9] with no previous urogynecological surgery were invited and enrolled in the study. After reading and signing the informed consent, patients were told about the study aims and if they had clinical contraindications for surgery or did not want to undergo surgery, they were allocated to the pessary group.

Exclusion criteria were: women with prolapse not assessed by POP-Q classification,[9] women who were using or who have used vaginal or oral antibiotics in the last 30 days of enrollment, and women who did not return to the clinic after placing the pessary. The type of pessary used was the ring type and this

device was removed and cleaned during a medical appointment every 3 months according to our outpatient protocol. During their follow-up consultation, women were assessed with a questionnaire regarding the presence of vaginal symptoms. All women used vaginal estrogens (estriol vaginal cream 3 times a week) and were advised to discontinue the use 3 days prior to vaginal collection and not to have sexual intercourse 24 hours before vaginal exam.

Vaginal Sampling and Microbiological Analysis

Women underwent gynecological examination with special attention for the presence of vaginal discharge, genital lesions and vaginal content collection. Clinical data were obtained by specific questionnaire. The vaginal content was collected by a single investigator, systematically through a swab applied to the left vaginal wall. The smear was performed on a glass slide and stained by the Gram stain technique. The reading of the slide was done by a single biologist specialized in microbiology, with large experience. Bacterial vaginosis was diagnosed by Nugent score,[10] vaginal microflora was classified as type 1 (lactobacilli), type 2 (40–50% lactobacilli presence) and type 3 (absence of lactobacilli plus predominance of coccobacilli). The scores used were from 0 to 4, according to the number of Gardnerella vaginalis and Bacteroides, species from 0 to 2, according to the number of Mobiluncus, and from 0 to 4 for the decrease in the number of lactobacilli. The total Nugent score is the sum of the three partial scores: type 1 flora is defined when the total score is from 0 to 3, type 2 flora or intermediate is defined when the score is from 4 to 6, and type 3 flora, with the diagnosis of bacterial vaginosis, is defined when the score is from 7 to 10.[11] Leukocytosis was considered present when the number of leukocytes was higher than 4/field of high magnification (1000x).

Statistical Analysis

The power calculation for this study considered a significance level of 0.05, a proportion of the pessary group of 0.64 and control group of 0.35 and a study power of 80%, giving a sampling of at least 45 women to each group. Statistical analysis was performed with SAS version 9.4 for Windows (SAS Institute, Cary, NC, USA). The characterization of the total sample was performed using simple and relative frequencies for the categorical variables and descriptive measures (mean and standard deviation) for the quantitative variables. For categorical variables, the chi-square test or Fisher exact test was applied and, for continuous variables, *t*-test was applied for variables with normal distribution and Mann-Whitney test was applied for non-parametric variables. A logistic regression model was created to assess which variables were independently associated with a higher prevalence of vaginal discharge, ulcer or vaginosis.

Results

Ninety women were included in the study, 45 women were in the pessary group and 45 women in the waiting surgery group. The mean age of the women in the pessary group was 73.5 (± 7.9) years, and in the surgery group it was 65.5 (± 7.6) years ($p < 0.05$). Most women (71.1%) were white and had only elementary school, with no difference between groups ($p = 0.89$). Moreover, there were no differences regarding the presence of comorbidities (hypertension, diabetes mellitus or chronic obstructive pulmonary disease) between the groups. The vast majority of the women did not smoke, were postmenopausal and did not use hormone therapy, with no statistical differences between groups ($p = 0.43$, 0.85 and 0.68, respectively). With regard to sexual activity, the women of the surgery group reported having more sexual activity than the women of the pessary group (33.3% versus 13.7%, respectively, $p = 0.03$) (►**Table 1**).

The women of the pessary group used the device for 14 months (± 8.1). No difference was noted with regard to the types of flora presented by the women in the two groups. Most of the women had type 1 flora (35.6% of the pessary group and 46.7% of the surgery group, $p = 0.50$). (►**Table 2**). Itching was reported in 20% of the pessary group versus 2.2% in the surgery group ($p < 0.05$). Vaginal discharge was observed in 84.4% of the pessary group during vaginal examination, and in 62.2% of woman in the control group ($p < 0.01$) (►**Table 2**); odds were 3.3 (confidence interval [CI] 1.2 to 9.01) times higher of presenting vaginal discharge in the pessary group.

Bacterial vaginosis according to Nugent criteria was 3 times more present in the study group (31.1%) than in the controls (22.2%), however, it was not significant ($p = 0.34$). There was no difference in the presence of candidiasis in the two groups ($p = 0.36$). Genital ulcers were present in 9 out 45 women of the study group (20%) ($p < 0.05$). Leukocytosis was significantly higher in the pessary group ($p < 0.05$) (►**Table 2**). Moreover, there was no association between the presence of ulceration and the presence of candidiasis ($p = 1$), bacterial vaginosis ($p = 0.14$), vaginal discharge ($p = 0.13$) and leukocytes ($p = 1$).

Multivariate analysis showed an association between higher prevalence of vaginal discharge, ulcer or vaginosis and the use of pessaries (►**Table 3**). There was no association with other variables (age, sexual activity, parity, menopause, use of pessaries).

Discussion

This study showed that women with POP who use pessary have more vaginal discharge, itching and genital ulcers than women that do not use pessary. Moreover, even if not statistically significant, BV was three times more prevalent in therapeutic pessary users. There was no difference with regard to the prevalence of vulvovaginal candidiasis. The increase of vaginal secretion could be related to the use of the pessary, but not to an infection that needed to be treated.

More than two thirds of the women in the pessary group had vaginal discharge. Studies have shown that discharge is a complaint constantly mentioned by pessary users.[4,5,7] A systematic review showed that vaginal discharge is the most frequent complication related to the use of pessary, occurring in 56% of the users.[6] The results of this study showed that vaginal discharge is very common in women

Table 1 Baseline characteristics of 90 patients with POP

	Pessary $n = 45$ (%)	Control (surgery) $n = 45$ (%)	*p*
Age (mean ± SD)*	73.5 (±7.9)	65.5 (±7.6)	< 0.001
Race*			
White	32 (71.1)	32 (71.1)	0.89
Black Mulatto	6 (13.3) 6 (13.4)	5 (11.1) 8 (17.7)	
Other	1 (2.2)	0	
Education*			
Elementary school	37 (82.2)	40 (88.9)	0.21
High school	1 (2.2)	3 (6.6)	
No education	7 (15.6)	2 (4.4)	
Comorbidities*			
Yes	33 (73.3)	32 (71)	1.00
No	12 (26.7)	13 (28.8)	
Smoking*			
Yes	2 (4.4)	5 (11.1)	0.43
No	43 (95.5)	40 (88.9)	
Menopause**			
Yes	45 (100)	43 (95.5)	0.85
No	0	2 (4.4)	
Hormone Therapy *			
Yes	2 (4.4)	4 (8.8)	0.68
No	43 (95.5)	41 (91.1)	
Sexual activity***			
Yes	6 (13.6)	15 (33.3)	0.03
No	38 (86.3)	30 (66.6)	

Note: *Fisher exact test; **Mann-Whitney test; ***Chi-square test
Abbreviations: POP, pelvic organ prolapse; SD, standard deviation.

Table 2 Gynecological and microbiological vaginal findings in women using and not using pessaries

Variables	Pessary $n = 45$ (%)	Control (surgery) $n = 45$ (%)	*p*
Vaginal Discharge*			
Yes	38 (84.4)	28 (62.2)	0.0171
Microbiological Flora*			
Type 1	16 (35.6)	21 (46.7)	
Type 2	15 (33.3)	14 (31.1)	0.5024
Type 3	14 (31.1)	10 (22.2)	
Ulcer**			
Yes	9 (20)	0	0.0025
Vaginosis (Nugent criteria)*			
Yes	14 (31.1)	10 (22.2)	0.3404
Vaginal Inflammation*			
Presence	32 (71.1)	3 (6.6)	< 0.0001

*Chi-Square; **Fisher exact test.

Table 3 Factors associated with the presence of leucorrhea and/or ulcers and/or bacterial vaginosis ($n = 87$)

Variable	Odds ratio	CI 95%	*p*
Use of pessary (Yes)	14.87	5.5 – 44.87	< 0.0001

Note: Variables that were analyzed and not associated: age, sexual activity, parity, menopause.
Abbreviations: CI, confidence interval.

using pessaries. All included women have used a ring pessary, which is the most used type of pessary according to the literature, with a frequency of 47% of leucorrhea.[6]

With regard to the vaginal content of the women included in this study, it can be observed that there was no difference between the types of flora in both groups. A recent study assessing the flora before and after one month of use of pessary also showed that the vaginal flora is not always changed by the use of pessary. Women who had normal lactobacilli before using pessary tend to have normal vaginal flora after use.[12] Type 1 flora predominantly consists of lactobacilli[10] and they are present when there is estrogen. In postmenopausal women, there is follicular depletion, with reduction in the levels of estrogen; for this reason, a type 1 flora is not expected in this group of women. However, all women in this study used vaginal estrogen 3 times a week, which explains the presence of this type of flora in women in this study.

The pessary group had women with an older age and with less sexual activity, but these did not affect the results according to logistic regression. The main variable associated with vaginal discharge was the utilization of pessaries.

Bacterial vaginosis was diagnosed in this study with Nugent criteria; we chose this classification because it seems to be less subjective than Amsel criteria. Bacterial vaginosis was identified in one third of the women who used pessary with no differences when compared with the surgery group. The findings of this study are different from another study that also showed higher prevalence of BV in pessary users (32% in pessary users and 10% in control)[7] and thus, it suggests the conclusion that the observed vaginal secretion in women with pessaries is not pathological. Collins et al[5] also concluded that Amsel and Nugent criteria were not adequate to analyze the microbiological flora from their patients; however, all recruited women were post-menopausal and used pessaries with no vaginal estrogen replacement, which may justify their results.

Women also complained about genital itching in 20% of the times; however, there was no difference in relation to the presence of vaginal candidiasis (observed in 8.9% of pessary users). This symptom may be related to a reactive process due to the presence of the pessary inside the vagina. To the best of our knowledge, there are no articles in the literature that evaluated vaginal candidiasis in pessaries users.

This study showed that women with pessary presented a significantly higher number of leukocytes in vaginal secretion, which may be explained by an inflammatory reaction caused by the use of the device.[5] Erosion or ulceration of the vaginal mucosa is a condition often associated with the use of pessaries.[13–16] But, in this study, ulceration was not associated with the presence of inflammation (an increase of leukocytes in vaginal secretion). Moreover, the presence of ulcer was not associated with vaginal discharge, BV or candidiasis. Ulcers may be caused by the pressure exerted by the pessary in the vaginal mucosa and are associated with the long uninterrupted use of the device or when it is too big.[6]

Serious complications such as fistula, which can evolve to infections and even death, are rare,[6] and were not found in this study. Moreover, no cases of vaginal cancer were observed.

This study has some limitations. Cross-sectional studies do not allow associations of cause and effect. We have treated all the women with BV, but we did not provide follow-up care. One possibility of other study is remove the pessary to chance modified the vaginal discharge. As women were not accompanied by a long-term option, it was impossible to infer how many women would no longer use the pessary because of complications. Moreover, the use of estrogen as part of the routine protocol may influence the vaginal flora, and in a certain way may be considered as a limitation

The strength of the study is that only one type of pessary was used and it is the one most widely used and studied.[6] In addition, vaginal bacterioscopy was performed on all women. Bacterioscopy is the gold standard for the assessment of vaginal discharge.

Given the increased life expectancy, there will be an increase in the incidence of POP in public health care.[17] Older women with POP or with associated comorbidities that may preclude surgical treatment could benefit from this conservative treatment.[2] The pessary is an effective method to treat POP. A systematic review demonstrates that the pessary can produce a positive effect on women's quality of life and can significantly improve sexual function and body perception, with few side effects and an impact to women's body image and sexual function.[2,18,19] There are some adverse events in the use of pessaries (such as common vaginal discharge) that could be a cause of abandon if the patient does not comprehend that this is simply an adverse event without major complications.

This study shows, in conclusion, that the use of pessaries may increase vaginal discharge; however, there is no increase of bacterial vaginosis or candidiasis. The increase of vaginal secretion is probably due to a foreign body-like inflammatory reaction.[20] This inflammatory reaction is not related to the presence of ulcers. Thus, women will unlikely abandon this treatment because of possible complications. Health providers should be prepared about how to counsel these women explaining that the increase of vaginal secretions does not represent an infection finding.

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