


Quality of life and vaginal symptoms of postmenopausal women using pessary for pelvic organ prolapse: a prospective study

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SUMMARY

OBJECTIVE: *The use of pessary is an option for the conservative treatment of pelvic organ prolapse (POP). However, here are few studies assess the quality of life (QoL) after inserting the pessary for POP. We have hypothesized that the use of pessary would modify QoL in women with POP.*

METHODS: *A prospective, observational study was performed that included 19 women with advanced POP. Pessary was introduced, and the SF-36 (general quality of life) and ICIQ-VS (vaginal symptoms and quality of life subdomain) questionnaires were applied before the introduction and after six months. A single question about the satisfaction regarding the use of the device was presented (subjective impression).*

RESULTS: *The mean age of the women included was 76 years. Most of them were non-caucasian (52.6%), with no prior pelvic surgery (57.5%), with urinary symptoms (78.9%). A third of the patients reported sexual activity. After treatment, 22.2% of them presented vaginal infection, and 27.7% increased vaginal discharge. Urinary symptoms remained unaltered. Women reported 100% satisfaction after using the pessary (77.7% partial improvement; 22.3% total improvement). SF-36 had significant improvement in three specific domains: general state of health ($p=0.090$), vitality ($p=0.0497$) and social aspects ($p=0.007$). ICIQ-VS presented a reduction in the vaginal symptoms ($p < 0.0001$) and an improvement in QoL ($P < 0.0001$).*

CONCLUSION: *The use of pessary for six months improved the QoL and reduced vaginal symptoms for women with advanced POP.*

KEYWORDS: *Pessaries. Pelvic organ prolapse. Quality of life. Surveys and Questionnaires.*

INTRODUCTION

Pelvic organ prolapse (POP) is a disease with high prevalence among older women and may impair their quality of life (QoL) significantly. Population aging is causing an increase in this estimative¹⁻³. POP symptoms can be described as pain, pelvic pressure, sexual dysfunction, urinary or bowel symptoms⁴.

Two general options for treating POP are avail-

able: conservative or surgical treatment. The pessary is the most important representative of this first choice and presents a good acceptance rate (85% success report) by women, despite some reports of discomfort and expulsion⁴⁻⁶. However, there aren't many studies focusing on this topic, especially in Brazil. A systematic review has found seven articles

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related to pessary and QoL and has concluded that the pessary produced a positive effect on women's health; they have also suggested that further studies are necessary⁷. Given that, we sought to assess, using validated questionnaires, the quality of life, symptoms, and complications of women that have used vaginal pessaries as a conservative treatment for POP.

METHODS

We performed a prospective, non-randomized study with nineteen women recruited at the Gynecology Outpatient Clinic of our Institution (CAISM-UNICAMP) from March 2015 to 2016. Institutional Review Board approved this study (CAAE - 19460013.5.0000.5404), and after signing a written informed consent, women were enrolled.

We included women with advanced POP (POP-Q stage 3 and/or 4) that would accept the use of vaginal pessary for conservative treatment. We excluded from the study women with no POP-Q clinical assessment or with cognitive dysfunctions that would disable them from answering the questionnaire.

The primary outcome was the quality of life measured by the questionnaires ICIQ-VS (International Consultation on Incontinence Questionnaire – Vaginal Symptoms) and SF-36 (Short Form 36 Health Survey). The ICIQ-VS is a validated questionnaire for Brazilian Portuguese comprising fourteen questions, divided into three independent domains: vaginal symptoms subscale (score 0-53), sexual matters subscale (score 0-58) and the overall impact on quality of life subscale (0-10)⁸. The SF-36 questionnaire is a general QoL instrument, divided into eight domains: vitality, physical functioning, bodily pain, general health perceptions, physical functioning, emotional functioning, social functioning, mental health⁹.

The secondary outcomes were: subjective impression about the use of a pessary (satisfaction), divided into cured, better, unaltered, worse; sociodemographic and clinical data; complications; and urinary symptoms.

After filling out the forms, a gynecological exam was performed with the measurement of the posterior cul-de-sac in centimeters with a colpometer and the choice of the pessary size, inserted in a gynecological position by a single health professional (S.C.A.C.). After insertion (device between the pubic bone and sa-

crum), the patient was oriented to walk after a spontaneous micturition. If she had no complaints, she was discharged with verbal orientations. A six-month follow-up was scheduled, and the same questionnaires were applied again during a follow-up visit.

Power calculation was performed; considering a mean difference of 17 (\pm 6) scores from the QoL questionnaires between the pessary users and non-users, a power of 80% and 0.05 alpha, with no drop-outs, we would need 18 women to perform this study¹⁰. Regarding statistical analysis, simple and relative frequencies were calculated for the categorical variables and descriptive measures (mean and standard deviation) for the quantitative variables. The Wilcoxon paired test was used to compare the questionnaire scores before and after treatment. Data were analyzed by the SAS (Statistical Analysis System) for Windows, version 9.4. A significance level of 5% was stipulated.

RESULTS

Twenty-seven women were enrolled in this study; eight were discontinued from the study (one patient deceased and seven failed to retain the pessary), and 19 completed the six-month follow-up. Mean age and BMI were 76 \pm 7.9 years and 24.7(\pm 3.5) kg/m², and most of the women (58%) were multiparous and non-caucasian (52.6%). The anterior (84.2%) and/or apical (74.4%) compartment were the most prevalent prolapse defects. A third of women were sexually active (Table 1).

Regarding the pessary model, all women used the ring format. Almost a third (27.8%) of the patients reported vaginal discharge. There were two cases of local pain, vaginal infection, and ulceration. No case of severe complication such as bleeding, fistula or malignant transformation was seen. About urinary symptoms, no difference was observed before and after using the pessary for six months.

When women were asked how satisfied they were with the use of the pessary, 77.7%(15/19) reported improvement and 22.3% (4/19) said they were cured. Table 2 displays the results from the applied questionnaires. The vaginal symptoms subscale from the ICIQ-VS improved significantly, with a 28-point decrease in the scores ($p=$.0001) as well as QoL, with a reduction of 8.1 points ($p=$.0001). No difference was seen concerning the sexual score; however, this subscale was underpowered ($n=4$) (Table 2). As for the SF-

36, a significant improvement was perceived in three specific domains: general state of health ($p=0.0090$), vitality ($p=0.0497$) and social aspects ($p=0.0007$).

DISCUSSION

The use of the pessary had a positive effect on advanced POP, with an improvement in women's QoL, a high success rate and no severe complications related to the use of the device. Our findings are also consistent with a systematic review previously published by our research group which showed that the pessary can produce a positive effect on women's quality of life and can significantly improve sexual function and body perception ⁷. Some studies also verified an improvement of POP symptoms that was comparable to the improvement seen after surgical

treatment [de Albuquerque Coelho, 2016, Female pelvic organ prolapse using pessaries: systematic review¹¹⁻¹³. Moreover, other studies have shown an improvement of the POP symptoms and QoL, as well as good indexes of body image and sexual function ^{10,14-16}.

However, we did not see any difference in the sexual matter subscale before and after treatment, probably because only a third of women were sexually active and this has perhaps underpowered the statistical analysis, increasing the risk of a type II error. A study that investigated the risk of sexual dysfunction (FSFI questionnaire) in a population of 73 women using pessaries for POP has found a significant improvement of 42.4% on the score, specifically concerning desire, lubrication and sexual satisfaction ¹⁵. Another study has used the PISQ-12 questionnaire for the same objective and compared it with women that underwent surgery; a significant improvement was seen in both groups ¹³. All women were using the ring pessary, and differently from obstructive pessaries, the ring model may be used during sexual intercourse.

We used the ICIQ-VS; its QoL subscale improved 80% after the pessary treatment; this result resembles the data from other studies that have shown an increase of at least 40% in the QoL scores, but using different questionnaires (P-QOL, PFIQ, SPS-Q) ^{12,14,16}. About the SF-36, a general QoL questionnaire, we

TABLE 1: BASELINE CHARACTERISTICS OF WOMEN SUBMITTED TO PESSARY TREATMENT FOR PELVIC ORGAN PROLAPSE.

Variables	N=19
Age (X± SD - years)	76±7.9
Age at menopause (X± SD - years)	48±5.2
Body mass index (kg/m ²)	24.7±3.5
Educational level (years)	
< 4	17 (89.5%)
4-11	2 (10.5%)
Comorbidities	15 (78.9%)
Number of pregnancies - n(%)	
1-3	8 (42%)
4- 9	7 (37%)
> 9	4 (21%)
Spontaneous vaginal delivery - n(%)	
1-3	9 (47%)
4-9	8 (42%)
>9	2 (11%)
POP-Q staging- n(%)*	
Apical compartment	14 (74.4%)
Anterior compartment	16 (84.2%)
Posterior compartment	13 (68.4%)
Previous Pelvic Surgery - n(%)	8 (42.5%)
Sexually active - n(%)	6 (31.6%)
Urinary symptoms - n(%)*	
Stress urinary incontinence	6 (31.6%)
Urgency	8 (42.1%)
Frequency > 7 micturitions	9 (47.4%)
Nocturia	8 (42.1%)

*More than one response may apply.

TABLE 2: QUALITY OF LIFE AND VAGINAL SYMPTOMS OF WOMEN USING PESSARY FOR POP BEFORE AND AFTER TREATMENT (N=19).

Questionnaires	Before treatment*	After treatment*	Mean difference	p value**
SF 36				
Physical functioning	59.7±31.6	76.1±23.8	16.4	0.0910
Physical role	31.6±47.8	5.3±22.9	-26.3	0.1250
Pain	73.5±21.6	82.6±13.1	9.2	0.1162
General Health	74.2±19.7	82.7±17.3	8.6	0.0090
Vitality	64.7±24.3	76.1±15.5	11.3	0.0497
Social functioning	59.9±34.8	94.7±16.3	34.9	0.0007
Emotional role	29.8±45.7	5.3±22.9	-24.6	0.1250
Mental health	60.4±20.6	65.7±19.1	5.3	0.1404
ICIQ-VS				
Vaginal symptoms	30.1±8.2	2.1±3.7	-28	< 0.0001
Sexual matters***	35.5±28.1	0.0±0.0	-35.5	0.5000
Quality of life	8.5±2.1	0.4±1.8	-8.1	<0.0001

*Mean±standard deviation; **Wilcoxon test; ***n=4.

noticed a significant improvement in the general health, vitality, and social aspects domains. Other studies did not use a generic QoL questionnaire but specific ones for pelvic floor dysfunctions^{10,12,13,15,17,18}. POP is a condition that impairs the QoL, and we included this questionnaire to understand more thoroughly the impact of the pessary treatment in women's lives^{16,18}.

The main complication found in this study after using the pessary was the increase of vaginal discharge, similar to what the literature describes. It is the most frequently referred symptom by women, followed by vaginal infection and the presence of ulceration. This increase in vaginal discharge is probably attributed to a foreign body in the vagina, as well as the possible presence of bacterial vaginosis and ulceration (19,20). We have already shown that the use of a vaginal pessary may interfere with the vaginal environment (84% of vaginal discharge in the pessary group versus 62.2% in the control group; $p < 0.01$)²¹. Fortunately, no severe complications (device entrapment or urogenital fistula) were seen in this study^{22,23}. As for pessary expulsion, seven women presented this; it is the risk factor most often associated with the discontinuation of the treatment according to the available literature; other reported conditions are pain and discomfort^{17,22,23}.

The strength of this study is the application of val-

idated questionnaires (one POP-specific and the other for general QoL assessment). As for its weaknesses, we have no control group and small sample size, even though the power calculation assures that we have recruited the minimum amount necessary to perform the study. Another point was the small percentage of sexually active women, which impaired our capacity to analyze this outcome.

CONCLUSION

Conservative treatment with the use of ring pessary for six months in women with POP presented significant improvements in the domains of two validated questionnaires of quality of life and vaginal symptoms. The SF-36 presented improvement in three specific domains: general state of health, vitality and social aspects. ICIQ-VS presented good scores in the domains of vaginal symptoms and quality of life.

Conflict of interests

None

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RESUMO

OBJETIVO: O pessário é uma opção para o tratamento conservador do prolapso genital.

MÉTODOS: Um estudo prospectivo e observacional foi realizado com 19 mulheres com prolapso genital avançado. A avaliação da qualidade de vida e dos sintomas vaginais foi mensurada pelos questionários SF-36 e ICIQ-VS antes e seis meses depois da colocação do pessário. Uma pergunta simples sobre satisfação do uso do dispositivo foi também feita (impressão subjetiva).

RESULTADOS: A idade média das mulheres foi de 76 anos. A maioria era parda/negra (52,6%), sem cirurgias pélvicas (57,5%), com sintomas urinários (78,9%). Um terço das pacientes relatou atividade sexual. Depois do tratamento, 22,2% apresentaram infecção vaginal e 27,7% fluxo vaginal aumentado. Não houve alteração da prevalência dos sintomas urinários. As mulheres relataram 100% de satisfação (77,7% melhora parcial e 22,3% melhora completa) depois do uso do pessário. Houve melhora em três domínios do SF-36: saúde em geral ($p=0,090$), vitalidade ($p=0,0497$) e aspectos sociais ($p=0,007$). O ICIQ-VS apresentou redução nos sintomas vaginais ($p < 0,0001$) e melhora da qualidade de vida ($p < 0,0001$).

CONCLUSÕES: O uso do pessário por seis meses em mulheres com prolapso genital melhorou a qualidade de vida e reduziu os sintomas vaginais.

PALAVRAS-CHAVE: Pessários. Prolapso de órgão pélvico. Qualidade de vida. Inquéritos e questionários.

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