

# ORIGINAL ARTICLE

## Özgün Araştırma

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## Vaginal Pessary vs Vaginal Pessary Combined with Local Estrogen: Genitourinary Effects in Postmenopausal Women with Pelvic Organ Prolapse

## Vajinal Pessere Karşılık Vajinal Pesser ve Lokal Östrojen Tedavisi: Pelvik Organ Prolapsusu Olan Postmenapozal Kadınlarda Genitoüriner Etkilerinin Karşılaştırılması

### ABSTRACT

#### Objective:

To compare the genitourinary effects of vaginal pessary and vaginal pessary combined with local estrogen in postmenopausal women with pelvic organ prolapse (POP) who did not wish to undergo surgery.

#### Method:

This prospective case-control study was conducted in the Gynecology Department of Turhal State Hospital and Tokat State Hospital between May 2021 and July 2021. Vaginal pessary ring was applied in 25 patients while vaginal pessary ring was administered in combination with local estrogen in 25 patients. Both groups were compared with respect to age, gravidity, parity, genitourinary symptoms, urinary incontinence, bacteruria, leukocyte count and C reactive protein (CRP) value.

#### Results:

When compared to the women using vaginal pessary in combination with local estrogen, the women who used vaginal pessary alone had pelvic pain and vaginal dryness significantly more and vaginal bleeding significantly less ( $p=0.034$ ,  $p=0.037$  and  $p=0.042$  respectively).

#### Conclusion:

Significantly higher incidence of pelvic pain and vaginal dryness in women using pessary alone can be attributed to the inflammatory effects of vaginal pessary which is associated with foreign body effect on vaginal mucosa. On the other hand, local estrogen may cause postmenopausal vaginal bleeding. Therefore, vaginal pessary in combination with local estrogen should be used carefully in postmenopausal women with POP.

#### Key Words:

Estrogens, Pelvic organ prolapse, Pessary, Vagina

**ÖZ****Amaç:**

Pelvik organ prolapsusu (POP) olup cerrahi tedavi istemeyen ve menopoz sonrası dönemde bulunan kadınlarda sadece vajinal pesser ve vajinal pesser ile beraber lokal östrojen kullanımının genitüriner etkileri karşılaştırıldı.

**Yöntem:**

Bu prospektif vaka-kontrol çalışması, Turhal Devlet Hastanesi ve Tokat Devlet Hastanesi Kadın Hastalıkları ve Doğum kliniklerinde Mayıs 2021 ve Temmuz 2021 tarihleri arasında gerçekleştirildi. Postmenapozal dönemde olup POP nedeniyle cerrahi uygulanmasını istemeyen 25 kadına sadece vajinal pesser ve diğer 25 kadına pesser ile birlikte lokal östrojen uygulandı. Gruplar; yaş, gravidite, parite, genitüriner belirtiler, üriner inkontinans, bakteriüri, lökosit sayımı ve C-reaktif protein (CRP) değerleri açısından karşılaştırıldı.

**Bulgular:**

Pesser ile birlikte lokal östrojen kullanan kadınlarla karşılaştırıldıklarında, sadece pesser kullanan kadınlarda pelvik ağrı ve vajinal kuruluk anlamlı olarak daha fazlaydı ancak vajinal kanama anlamlı olarak daha azdı (sırasıyla  $p=0.034$ ,  $p=0.037$  ve  $p=0.042$ ).

**Sonuç:**

Sadece pesser kullanan kadınlarda pelvik ağrı ve vajinal kuruluk belirtilerinin anlamlı olarak daha fazla görülmesinin nedeni, östrojenden yoksun vajinal mukozada yabancı cisim etkisiyle vajinal inflamasyonun artması olabilir. Öte yandan, lokal östrojen kullanan hastalarda vajinal kanama anlamlı olarak daha fazla görülmüştür. Vajinal pesser ile lokal östrojen, postmenopozal POP tedavisinde dikkatli bir şekilde uygulanmalıdır.

**Anahtar Kelimeler:**

Östrojen, Pelvik organ prolapsusu, Pesser, Vajina

**INTRODUCTION**

Pelvic organ prolapse (POP) is defined as the downward migration of structures within the pelvis because of anatomic or functional disorders in the structures supporting the pelvic organs (1). Age, menopausal status, pregnancy, vaginal birth, obesity, chronic cough, chronic constipation, work stress, congenital factors, and history of hysterectomy are significant risk factors for POP (2-7). Since vaginal pessaries are non-invasive, economical and immediately effective medical tools, their use has become more popular in recent years. The main indications for the application of vaginal pessaries are the risk for surgery and the wish for the preservation of fertility. In order to achieve success with vaginal pessary, the shape and size of the pessary to be used should be chosen fittingly and the patient compliance should be evaluated carefully (8,9). It has been reported that complaints such as the feeling of pressure and sagging are eliminated in 71%-90% of patients who use pessaries. Estrogen is usually prescribed for patients undergoing surgery but studies related to this have provided limited information. In a study by Felding et al, no clinical benefits have

been demonstrated with the use of vaginal estrogen treatment prior to POP surgery (10). Local estrogen treatment reduces the incidence of urinary tract infection when used during the perioperative period in patients undergoing POP surgery. However, there is not sufficient evidence to be able to say whether local estrogen has positive or negative effects on the efficacy of POP treatment (11,12). This study aims to compare the genitourinary effects of vaginal pessary and vaginal pessary combined with local estrogen in postmenopausal women with pelvic organ prolapse (POP) who did not wish to undergo surgery.

**MATERIAL and METHODS**

This prospective case-control study was conducted at the Gynecology Departments of Turhal State Hospital and Tokat State Hospital between May 2021 and July 2021. Approval for the study was granted by the Ethics Committee of Tokat Gaziosmanpaşa University (No:21-KAEK-092). All research reported in this manuscript was conducted in accordance with the principles set forth in the Helsinki Declaration 2008. Written informed consent was obtained from all patients. The study included a total of 50 postmenopausal women, aged 50-70 years, who were diagnosed with POP and did not wish to undergo surgery. Patients with vaginal infection, urinary system infection, and those who had surgery for POP were excluded. Only vaginal pessary was applied to 25 women who were in the postmenopausal period and did not want surgery due to POP, and local estrogen was applied to the other 25 women with pessary. Groups were determined according to patient wishes. A number 6 latex ring pessary was applied vaginally in 25 patients and a number 6 latex ring pessary in combination with local estrogen treatment was administered vaginally in the remaining 25 patients. The procedure for cleaning the pessary was explained to all patients and it was made sure that the cleaning procedure was performed twice a week. Local estrogen was applied vaginally as a 0.1% cream twice a week. Data related with age, gravidity and parity were acquired from hospital files. Genitourinary symptoms, urinary incontinence, bacteriuria, leukocyte count and serum C-reactive protein (CRP) levels were recorded at the beginning of the study and three months later.

**Statistical Analysis**

Collected data were analyzed by Statistical Package for Social Sciences version 20.0 software (SPSS IBM, Armonk, NY, USA). Continuous variables were expressed as mean  $\pm$  standard deviation while categorical variables were denoted as numbers and percentages. Mann Whitney U-test, independent samples t-test and chi-square test were used for the comparisons. A p value  $<0.05$  was accepted as statistically significant.

**RESULTS**

Table I shows the clinical characteristics of the patients treated with vaginal pessary ring alone and those treated with vaginal pessary ring in combination with local estrogen applied vaginally. Both patient groups were statistically similar in aspect of age, gravidity and parity respectively;  $p=0.553$ ,  $p=0.304$  and  $p=0.451$  Similarly, no statistically significant difference was

determined between the patient groups with respect to vaginal discharge, urinary incontinence and bacteriuria ( $p=0.384$ ,  $p=0.082$  and  $p=0.552$ , respectively). Both patient groups were also statistically similar in aspect of leukocyte count and serum CRP levels ( $p=0.107$  and  $p=0.118$  respectively). When compared to the women using vaginal pessary in combination with local estrogen, the women who used vaginal pessary alone had pelvic pain significantly more (4% vs 16%,  $p=0.034$ ) and vaginal dryness significantly more (0% vs 12%,  $p=0.037$ ) and vaginal bleeding significantly less (12% vs 2%,  $p=0.042$ ).

**Table 1:** Clinical characteristics of patient groups. Pessary alone vs Pessary combined with local estrogen

	Pessary alone (n=25)	Pessary combined with local estrogen (n=25)	p
Age (years)	56.32±9.41	54.76±9.64	0.553
Gravidity	2(0-4)	2(0-4)	0.304
Parity	2(0-3)	2(0-3)	0.451
WBC (K/uL)	7.84±3.45	9.28±3.22	0.107
CRP (mg/L)	1.64±0.83	1.3±0.64	0.118
Bacteriuria	2(4%)	1(2%)	0.552
Vaginal pain	8(16%)	2(4%)	<b>0.034*</b>
Vaginal dryness	4(8%)	0	<b>0.037*</b>
Vaginal discharge	4(8%)	2(4%)	0.384
Vaginal bleeding	1(2%)	6(12%)	<b>0.042*</b>
Urinary incontinence	5(10%)	1(2%)	0.082

\* $p<0.05$  was accepted as statistically significant.

## DISCUSSION

In literature, the success of pessary treatment for POP has been reported to differ between 15% and 59% (17, 18). Farrell et al., reported that complaints were eliminated or reduced in 59 of 100 patients with urinary incontinence who selected to try pessary treatment (13).

The most frequent complications related with pessaries are the dislodgement of the pessary, rectal pain, urinary incontinence, and vaginal dryness (7). Bacterial vaginosis has been reported to develop 4-fold more in pessary users than healthy women (7,14).

In a study by Dessie et al., women using vaginal estrogen were observed to have more vaginal discharge and a greater need to use pessaries than those not using estrogen (15). According to the results of another study by Tontivuthikul et al., there was no significant advantage of applying vaginal estrogen once a week compared to pessary use (16). It has been reported that urinary dysfunction occurs in 4% of pessary users (17,18).

In a multi-centre, double-blind and placebo-controlled study by Simunic et al., 1612 patients with urogenital symptoms were randomized and given vaginal 17-beta estradiol for 12 months. The general success rate was found to be 85.5% in the treatment group and 41.4% in the placebo group. Complaints such as a burning feeling when urinating, frequent urination, urine leakage, urgency, which were defined as urogenital atrophy symptoms, and more than two urinary tract infections within the

last year, had the incidences of 35.9% and 15.5% respectively in the treatment group (19). Previous researchers have concluded that vaginal estrogen treatment is an effective and safe option for the treatment of urogenital atrophy symptoms in postmenopausal women (19). The results of the meta-analysis published by the Cochrane working group in 2012 stated that although vaginal estrogen treatment generally provided an improvement or full cure for the complaint of urine leakage, it caused an increase in vaginal bleeding (20). In other studies related to the use of estrogen cream before POP surgery, no change in vaginal wall thickness has been reported, but there has been an increase in vaginal cytological maturation index by 15.5% (21).

This study investigated 25 women who used vaginal pessary alone and 25 women who used vaginal pessary combined with local estrogen within a period of 3 months. It was demonstrated that pelvic pain and vaginal dryness were observed significantly more in the patients treated with pessary alone and vaginal bleeding was observed significantly more in the patients using pessary combined with local estrogen. However, both patient groups were statistically similar in aspect of vaginal discharge. The findings of the present study should be interpreted carefully as their power is limited by relatively small cohort size, lack of randomization and long term data.

## CONCLUSION

POP is an important urogynecological problem which is encountered in women with advancing age. Treatment methods include local estrogen, pessaries, and surgery. In the current study, significantly higher incidence of pelvic pain and vaginal dryness in women using pessary alone can be attributed to the inflammatory effects of vaginal pessary which is associated with foreign body effect on vaginal mucosa. On the other hand, local estrogen may cause postmenopausal vaginal bleeding. Therefore, vaginal pessary in combination with local estrogen should be used carefully in postmenopausal women with POP.

### Ethics Committee Approval:

The Ethics Committee approval was received for the study. Approval for the study was granted by the Ethics Committee of Tokat Gaziosmanpasa University (No:21-KAEK-092). All patients provided informed consent.

### Peer-review:

Externally peer-reviewed. Author Contributions: Concept – B.Ş. and G.C.Ş.; Design - B.Ş. and G.C.Ş.; Supervision - B.Ş. and G.C.Ş.; Resources – B.Ş. and G.C.Ş.; Materials – B.Ş. and G.C.Ş.; Data Collection and/or Processing - B.Ş. and G.C.Ş.; Analysis and/or Interpretation - B.Ş. and G.C.Ş.; Literature Search - B.Ş. and G.C.Ş.; Writing - B.Ş. and G.C.Ş.; Manuscript - B.Ş. and G.C.Ş.; Critical Review - B.Ş. and G.C.Ş.

### Conflict of Interest:

The authors have no conflict of interest to declare.

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