International Urogynecology Journal (2019) 30:2161–2169
https://doi.org/10.1007/s00192-019-03919-8

ORIGINAL ARTICLE

Effectiveness of ring pessaries versus vaginal hysterectomy for advanced pelvic organ prolapse. A cohort study

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Received: 16 December 2018 / Accepted: 1 March 2019 / Published online: 12 March 2019

Abstract

Introduction and hypothesis This study aimed to evaluate the efficacy of the ring pessary compared with surgery as a primary treatment for advanced pelvic organ prolapse (POP) in non-hysterectomized, postmenopausal women. Our starting hypothesis was that the pessary is as effective as and less risky than surgery.

Methods This study was a prospective observational study, which recruited 171 women with symptomatic advanced POP in a tertiary hospital for 30 months. They were treated according their preference with either surgery [77/171 (45.0%)] or vaginal ring pessary without support [94/171 (55.0%)]. The primary outcomes included the discontinuation of pessary use and the incidence of recurrent prolapse throughout the study. Secondary outcomes included complications categorized according to Clavien-Dindo classification. Descriptive statistics were used for demographic data. The mean and standard deviation were calculated for continuous variables, and continuity correction tests, Mann-Whitney U tests, and Fisher's exact tests were used for categorical variables.

Results There was successful use of a pessary in 84.4% (76/90) of cases, and 89.6% (69/77) of patients did not have prolapse recurrence in the surgical group (>POP-Q 2). In the pessary group, the adverse event rate was 31.6%, and all were Clavien-Dindo grade I. Thirty patients [30/77 (39.0%)] had complications in the surgery group: 14.3% were Clavien-Dindo grade I (11/77), 10.4% were grade II (8/77), and 14.3% were grade III (11/77).

Conclusions The pessary is effective and has mild adverse events in non-hysterectomized, postmenopausal women with advanced POP.

Keywords Advanced pelvic organ prolapse · Adverse events · Efficacy · Ring pessary without support · Vaginal hysterectomy

Introduction

Pelvic organ prolapse is a common medical condition. As the population ages, the number of women suffering from pelvic floor disorders is increasing. Pelvic organ prolapse (POP) affects up to 50% of parous women [1], and the lifetime risk of a female patient requiring POP surgery has increased from 11% to 19% [2, 3]. Treatment options for symptomatic prolapse include pelvic floor muscle training (PFMT), pessary use, and surgery.

A robust evidence base has recently emerged regarding the role of PFMT in the treatment of pelvic organ prolapse. Women who received PFMT showed a greater subjective improvement in prolapse symptoms [4] and an objective improvement in POP severity [5]. Finally, PFMT remains a key factor in the treatment of urinary incontinence (UI) [6].

Vaginal pessaries are considered a first-line treatment option to correct POP in the USA [7]. Conversely, the European Menopause and Andropause Society (EMAS) clinical guide indicates the pessary is an alternative to surgical treatment for symptomatic elderly women, for women who wish to become pregnant, or for those who prefer nonsurgical treatment [8].

There is wide variation in the efficacy rates of pessary use among different populations worldwide and even within individual countries [8]. A recent systematic review identified the ring pessary model as the most frequently used device in the

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reviewed studies. The ring model is more widely used because it is easier to insert and has better acceptance because it fits better in the vagina. This model allows sexual activity without device removal and has the fewest complications, as described in the literature [9, 10].

Several studies have evaluated the success of pessary fitting, with success rates ranging from 41% to 74% [11].

In a prospective cohort study, postmenopausal women with symptomatic, advanced-stage POP fitted with a ring (without support) pessary had a success rate of 80.8% after a median of 27 months of follow-up [12].

POP surgery reduces the burden related to pelvic floor symptoms by restoring the anatomy of the vagina and surrounding visceral organs [13]. Unfortunately, POP surgery can be associated with complications. Furthermore, there are significant costs for prolapse surgery, particularly when the index surgery has a quoted failure rate of up to 30%[14].

According to two prospective trials comparing pessary treatment with POP surgery, women treated with a pessary and women treated with surgery reported similar improvements in urinary and bowel symptoms, sexual function, and quality of life [15, 16]. Although POP surgery has several advantages over pessary treatment, the risk of complications is higher, and it might be less cost-effective. Since previous studies have shown promising results with pessary treatment, it might be an equivalent option in the treatment of POP, probably with less risk and lower cost [17]. To our knowledge, there are no randomized controlled trials (RCTs) comparing the effectiveness and outcomes of pessary treatment versus surgery. The aim of this prospective observational and descriptive study was to compare the outcomes of a pessary or surgery in women with symptomatic POP, and the hypothesis was that continuous use of a ring pessary (without support) is as effective as and less risky than surgery in non-hysterectomized, postmenopausal Spanish women with advanced-stage POP using the Pelvic Organ Prolapse Quantification system (POP-Q).

Materials and methods

Study participants

We performed this prospective cohort group study comparing pessary treatment and prolapse surgery as primary treatments for POP at the Department of Obstetrics and Gynaecology, Macarena Hospital, Medical School, Seville University, Spain. Between January 2013 and June 2015, 171 non-hysterectomized, postmenopausal patients with symptomatic POP (stages III and IV) were counselled about the two treatment options: surgery or vaginal pessary. The interventions were either pessary treatment or POP surgery following patient preference. The inclusion criteria were non-hysterectomized, postmenopausal patients with symptomatic POP (stages III and IV) who agreed to use the vaginal ring pessary as treatment. Women who had a mental illness or who refused to participate in this study were excluded. Ninety-four patients (age range, 47–90) agreed to use the vaginal ring pessary, and 77 (age range 50-87) chose vaginal hysterectomy. The follow-up period was up to January 2017. All women were followed for a minimum of 18 months (range, 18-49 months) after the start of their pessary use or after surgery. This study was approved by the Ethics Committee of the Hospital Virgen Macarena (register no. 1168-N-17).

Study design

During the first visit, we recorded detailed information about the patients, including age, parity, body mass index, sexual status, medical comorbidities, constipation, chronic cough, smoking status, and prolapse symptoms, and we performed physical examinations. We classified urinary symptoms using the questions classically included in the International Consultation on Incontinence Questionnaire (ICIQ)[18] to distinguish between urgency urinary incontinence, stress urinary incontinence, mixed urinary incontinence, and voiding difficulties. For data analysis, replies of “never” or “rarely” were recorded as “no”, whereas replies of “sometimes”, “usually”, or “always” were recorded as “yes”. The POP-Q [19] was used to stage patients by a single, experienced gynaecologist. In this study, we categorized surgical complication severity according to a standardized severity scale, the Clavien-Dindo classification [20, 21]. A telephone hotline number was given to all patients in this study for early consultation if needed.

Pessary treatment

As previously described [12], for patients who chose the pessary, we decided to use only the ring pessary without support. That choice let us reduce potential bias, and there is no evidence showing that any particular type of pessary is superior to another [21]. The same gynaecologist chose the size of the ring pessary, and all pessaries were made of silicone (Corysan, Barcelona, Spain). A pessary was the correct size when the physician could place a single finger between the pessary and the vaginal wall, the prolapse was reduced to above the hymen, it felt comfortable to the patient, and it was retained during a Valsalva manoeuvre and coughing in both supine and standing positions. A topical oestrogen cream (10 mg/g Promestriene cream, 0.5 g each time, twice a week) was regularly prescribed to patients without any contraindications to protect the vaginal epithelium. We instructed the patient on how to prevent expulsion during defecation. Additionally, we taught the patient to palpate the pessary and hold it in place

during Valsalva or alternatively by squeezing her labia and thus closing the vaginal outlet.

All the women were asked to return in 1 week for an assessment after the initial fitting. The fitting was considered successful if the user felt comfortable with pessary use and wanted to continue to use it. If the pessary fell out or the patient experienced discomfort in the 1st week, they were refitted with a differently sized ring pessary and were reviewed again after another week. A maximum of three attempts was made to achieve successful pessary fit.

In this study, we did not advise periodically removing or replacing the pessary independently. For this reason, all patients were monitored monthly at the 1st and then every 6 months. Speculum and bimanual pelvic examinations were performed without removing the pessary at every visit to detect vaginal discharge, vaginal bleeding, or vaginal erosion; to assess whether the pessary was adequately relieving the patients' symptoms; and to review pessary maintenance. At these visits, the pessary was not removed, rinsed, or replaced if there were no adverse events. The patients were counselled to call us if vaginal odour, discharge, or bleeding occurred because these symptoms would warrant investigation for infection or erosion.

A successful fit was defined as a patient who continued pessary use until the end of the study or a patient who had a pessary expulsion and was refitted with a new pessary and continued its use. Adverse events were evaluated in patients with successful fittings. In women who experienced an increase in vaginal discharge or bleeding, a speculum examination was carried out without removing the pessary to look for erosions or abrasions. If erosions were present, the pessary was removed for 2 weeks, and local daily oestrogen was advised. Other causes of postmenopausal bleeding were investigated with vaginal sonography. If a vaginal pessary was not able to be fitted, conservative management or surgery was discussed. Patients who discontinued the pessary within the study period and were unable to be refitted were categorized as having an unsuccessful fitting. According to the study design, patients lost to follow-up were defined as discontinuations.

Surgical intervention

The surgical intervention consisted of correction of all compartments that required surgery. All the patients had uterine descent, so in all cases a vaginal hysterectomy was performed. Cystocele repair involved conventional anterior colporrhaphy. A coexisting rectocele was treated with conventional posterior colporrhaphy. When stress incontinence was diagnosed prior to surgery, the patient and surgeon decided first to perform prolapse surgery only, with additional incontinence surgery later.

We analysed the results of the 15 surgeons who performed the operation at least once as the main surgeon during the observation period. When the first surgeon was a Registrar, the assistant always had surgical experience defined as > 10 years registering at least once as the main surgeon in POP operations.

All procedures were performed under general or spinal anaesthesia. Prophylactic antibiotics were given preoperatively (cefazolin 2 g iv). As a prophylaxis for thromboembolism, low-molecular-weight heparin was administered subcutaneously pre- and postoperatively. The data collected included the type of surgery, procedure time, length of hospital stay, and perioperative complications. A urethral catheter was left in situ and was removed on the 1st postoperative day in women with anterior colporrhaphy. If the procedure was complicated by bladder lesions, the catheter was removed after 1 week. If urine retention occurred after removal of the catheter on the 1st day, the catheter was reinserted for another day.

We analysed patient- and surgeon-reported outcomes and defined the cure rate, our main outcome measurement, in terms of the absence or presence of a patient reporting feeling a genital protrusion and its presence at clinical examination during the observation period.

In addition, we examined resource parameters (operation time and length of hospital stay) and complications requiring medical attention during hospital stay and after hospital discharge by readmission to the hospital or at the first follow-up visit 1 month after surgery and at the end of the study.

Efficacy and adverse events

The success rate of ring pessary use and surgery and the incidence of adverse events were evaluated. Primary and secondary outcomes were determined a priori. The primary outcome included discontinuation of pessary use and the reasons for discontinuation or the incidence of recurrent prolapse in any vaginal compartment (anterior, posterior, or apical). Recurrent prolapse was defined as prolapse extending beyond the hymen (>POP-Q 2) with straining or repeat treatment for prolapse with either pessary or surgery. Secondary outcomes included the presence of increased vaginal discharge and the development of erosions and vaginal bleeding in pessary users and complications in the surgery group categorized according to a standardized severity scale: Clavien-Dindo classification [20, 21]. A recent study documented that all five Clavien-Dindo complication grades occurred because of pessary use. Grade I complications include deviations from the standard course of therapy, such as vaginal discharge, ulceration, pain, bleeding, constipation, material allergy, and the inability to replace or insert the pessary oneself. Grade II includes complications that require pharmacological treatment, such as vaginal discharge, erosion, vaginitis, ulceration, and acute pyelonephritis. Grade III complications require surgical or radiological

interventions, such as vesicovaginal or rectovaginal fistula, ureteric obstruction, retained pessary requiring surgical removal, decubitus ulceration of the uterus, hydronephrosis, bowel obstruction, or vaginal fibrosis. Grade IV includes life-threatening complications and organ dysfunction (vaginal or cervical cancer and small bowel incarceration). Grade V includes the death of a patient from incarceration, enterovesical fistula, or obstructive uropathy urosepsis [22].

Statistical analyses

Descriptive statistics were used for the demographic data. The mean and standard deviation were calculated for continuous variables. Continuity correction tests, Mann-Whitney U tests, and Fisher's exact tests were used to compare categorical variables as appropriate. We performed a post-hoc power analysis on the two main results of the study: effectiveness and adverse events.

$p < 0.05$ was considered statistically significant. SPSS v23.0 (IBM España SA, Madrid, Spain) was used to perform the statistical analyses.

Results

A total of 171 advanced POP patients (stages III and IV) were identified between January 2013 and June 2015. A total of 94 (54.0%) women expressed a treatment preference for the ring pessary, and 77 (45.0%) underwent surgical intervention. In this study, no patients were lost during follow-up. Table 1 shows the baseline characteristics of the study population. The pessary group was significantly older than the surgery group. Additionally, patients in the pessary group had a higher rate of rheumatological diseases, lumbar disc herniation, anticoagulation therapy, and history of lower urinary tract symptoms ($p < 0.001$). All women in both groups had advanced POP-Q (stages III/IV). There were significant differences in preoperative POP-Q and the prolapse stage in the anterior ($p < 0.05$) and posterior ($p < 0.001$) compartments.

Data on the treatment in the pessary group are presented in Table 2. Eight different pessary sizes were used for successful pessary fittings in this study. The median follow-up time was 24 months (range, 18–49 months). The ring pessary was fitted in 94 patients at the initial visit. Fourteen [14/94 (14.9%)] patients discontinued pessary use. After discontinuing pessary use, these patients all opted for surgery. Four [4/94 (4.3%)] patients died from non-pessary-related causes during the study [stroke ($n = 2$), pneumonia ($n = 1$), and aortic thrombosis ($n = 1$)]. Pessary use was continued by 76 [76/94 (80.8%)] women at the end of the study. If we excluded the four patients who died from non-pessary-related causes, the efficacy of the pessary was 84.4% (76/90).

Thirteen [13/94 (13.8%)] patients who had extrusion of the pessary during daily activities in the 1st week opted for reinsertion. Nine [9/94 (9.6%)] patients switched to larger pessaries, one [1/94 (1.1%)] switched to a smaller pessary, and three [3/94 (3.2%)] opted for a pessary of the same size.

Adverse events were evaluated in the patients with successful fittings at the end of the study. The most common adverse event was extrusion of the pessary during defecation or daily activities. All adverse events in that group of patients [24/76 (31.6%)] were of Clavien-Dindo grade I.

The surgery group's treatment data are presented in Table 3. Transvaginal hysterectomy and anterior colporrhaphy with native tissue were the interventions performed in most women [47/77 (61%)]. Sixty-nine patients (69/77) did not have any prolapse by the end of the study (at the 27-month median follow-up), resulting in a success rate of 89.6%. A total of eight patients [8/77 (10.4%)] met the composite definition of prolapse recurrence with prolapse beyond the hymen and/or retreatment. Using the POP-Q classification, six [6/8 (75%)] patients had a third-stage vault prolapse, and the other two patients had a fourth-stage vault prolapse.

Major intra- and postoperative complications are listed in Table 3. The only case of an intraoperative complication [1/77 (1.3%)] was a bladder injury; it was detected and treated immediately, followed by a week with an indwelling urethral catheter.

Using the Clavien-Dindo classification, we found grade 1 events in 11 patients [11/77 (14.3%)], grade 2 events in 8 cases [8/77 (10.4%)], and grade 3 events in 11 women [11/77 (14.3%)] (4 grade 3a and 7 grade 3b).

Table 4 shows the effectiveness and adverse event rates in both treatment groups. At the end of the study, the successful use of a pessary was 84.4%, and 89.6% of patients in the surgical group did not complain of any prolapse recurrence ($p = 0.115$). The post hoc power of the study to find differences in the effectiveness of pessary versus surgery was 44.1% with $p = 0.115$ and partial eta squared of 0.025. During analysis of complications, there was a significant difference between groups when Clavien-Dindo grades were considered ($p < 0.001$). The post-hoc power to find a difference in Clavien-Dindo stage between the two groups was 99.8% with $p < 0.001$ and partial eta squared of 0.15744.1%.

Discussion

Management of POP has changed over time because of the progressive understanding that connective tissue deficiency is the main contributor in the pathophysiology of POP [23]. Decision-making processes for clinicians are becoming more complex, with several procedures and conservative or surgical approaches to correct apical prolapse being described in the literature with different POP recurrence rates. Currently, it is

Table 1 Patient characteristics in the pessary and surgery groups

Characteristics	Surgery $n = 77$	Pessary $n = 94$	p value
Mean age, years, ± SD	64.7 ± 8.1	68.0 ± 8.8	0.012[a]
Mean age of menopause, years, ± SD	49.9 ± 4.3	50.2 ± 4.0	0.396[b]
Mean gravidity ± SD	3.5 ± 2.0	3.6 ± 1.4	0.260[b]
Mean vaginal deliveries ± SD	3.2 ± 1.7	3.3 ± 1.2	0.229[b]
BMI > 25 kg/m^2 *n* (%)	30 (39)	26 (27.6)	0.117[c]
Medical comorbidities, *n* (%)	70 (90.9)	91 (96)	0.102[c]
Diabetes, *n* (%)	21 (27.3)	20 (21.2)	0.361[c]
Cardiovascular diseases, *n* (%)	41(53.2)	62 (65.9)	0.091[c]
History of breast cancer, ovary, and/or bowel cancer, *n* (%)	3 (3.9)	4 (4.4)	1[d]
Tamoxifen therapy, *n* (%)	1 (1.3)	4 (4.4)	0.380[d]
Rheumatological diseases, *n* (%)	26 (33.8)	65 (69.1)	< 0.001[c]
Lumbar disc herniation, *n* (%)	4 (5.2)	22 (23.4)	0.001[c]
Anticoagulation therapy, *n* (%)	1 (1.3)	16 (17.0)	0.001[c]
Smoking, *n* (%)	8 (10.4)	8 (8.5)	0.675[c]
Chronic cough, *n* (%)	0	8 (8.5)	0.009[d]
Prior abdominal surgery, *n* (%)	16 (20.8)	20 (22.2)	0.937[c]
Prior incontinence surgery, *n* (%)	5 (6.5)	14 (15.6)	0.082[c]
History of lower urinary tract symptoms	36 (46.7)	79 (84)	< 0.001[c]
Stress	10 (13)	35 (37.3)	
Urge	8 (10.4)	44 (47)	
Voiding difficulty	8 (10.4)	52 (55.3)	
Preoperative POP Q stage%			0.004[c]
3	63 (81.8)	58 (61.7)	
4	14 (18.2)	36 (38.3)	
Stage of anterior compartment			0.027[c]
0	13 (16.8)	8 (8.5)	
1	13 (16.8)	17 (18)	
2	5 (6.4)	21 (22.3)	
3	46 (59.7)	47 (50)	
4	0	1 (1.1)	
Stage of apical compartment			0.102[c]
1	0	1 (1.1)	
2	11 (14.2)	4 (4.2)	
3	54 (70.1)	75 (79.7)	
4	12 (15.5)	14 (14.8)	
Stage of posterior compartment			< 0.001[c]
0	56 (72.7)	30 (31.9)	
1	14 (18.1)	45 (47.8)	
2	5 (6.5)	9 (9.6)	
3	2 (2.5)	10 (10.6)	
4	0	0	

SD, standard deviation; BMI, body mass index

[a] Independent sample *t*-test

[b] Mann-Whitney U test

[c] Continuity corrected chi-squared test

[d] Fisher's exact test

Table 2 Data from initial treatment in the pessary group

	Value	
Type of pessary (n = 94), ring without support	94 (100)	
Size of ring pessary used (n = 94) n (%)		
60 mm	1 (1.1)	
65 mm	1 (1.1)	
70 mm	7 (7.4)	
75 mm	39 (41.5)	
80 mm	19 (20.2)	
85 mm	16 (17)	
90 mm	9 (9.6)	
95 mm	2 (2.1)	
Continuation rates (n = 94), n (%)		
1 week	87 (92.6)	
1 month	85 (90.4)	
6 months	82 (87.2)	
12 months	80 (85.1)	
End of the study (median follow-up, 24 months Range (18–49 months)	76 (80.8)	
Reason for discontinuation (n = 18), n (%)		
Death of patient from non-pessary-related causes	4 (22)	
Feeling of discomfort	9 (50)	
Extrusion of pessary during daily activities	3 (16)	
Bleeding	1 (5.5)	
Dislike of the ring pessary by the husband	1 (5.5)	
Adverse events (n =76), n (%)		Clavien-Dindo classification
Extrusion of pessary during daily activities	14 (18.4)	Grade 1
Bleeding because of erosion	8 (10.5)	Grade 1
Vaginal discharge	1 (1.3)	Grade 1
Vaginal pain	1 (1.3)	Grade 1

also necessary to consider the personal desire of the women to choose uterine preservation through conservative and surgical options [24].

This study was a prospective, observational, non-randomized study comparing pessary treatment and surgery as primary treatments for advanced POP. We included a group of 171 postmenopausal women with third- or fourth-degree vaginal prolapse who expressed their preference for conservative or surgical intervention. All were examined by only one senior gynaecologist. Therefore, the measurements of POP-Q were consistently quantified. Patients in the surgery group were significantly younger than those in the pessary group, which could have produced selection bias because the groups were not randomized, but the heterogeneity between treatment groups reflected normal daily practice. The POP-Q stages of the pessary group were also higher, a result consistent with other studies in the literature [17], without differences in the above symptoms.

The efficacy was similar in both treatment groups. In the pessary group, the success rate was 84.4%, and it was 89.6% in the surgery group, which was not a statistically significant difference (p = 0.115). There is a very wide variety of definitions of success in pelvic prolapse surgery. Kowalski [25] found 26 different definitions of anatomic success and 11 ways to define subjective success. We decided to define success as a combined definition of absence of vaginal bulge and not needing retreatment because it is more clinically relevant for patients. Consequently, considering efficacy, we can assert that there were no differences between the two options for treatment for POP.

Several studies evaluated the complications of successfully fitted ring pessaries, with rates ranging from 56 to 58% [17]. In our study, the adverse event rate was 31.6%, which was lower than in the previous studies, and all were Clavien-Dindo grade I. For the 77 patients in the surgical group, we found a postoperative vault prolapse rate of 9.1% (7/77), while in the literature, the prevalence of post-hysterectomy vault prolapse has been reported to range from 0.2% to 43%. However, recent data suggest an incidence of 11.6% following hysterectomy for prolapse and 1.8% for other pathologies [26]. Our

Table 3 Treatment data for the surgery group

	Value	
Type of operation (n = 77), n (%)		
TVH	24 (31.2)	
TVH + ACR	47 (61.0)	
TVH + ACR + PCR	4 (5.2)	
TVH + PCR	1 (1.3)	
TVH + ME	1 (1.3)	
Operative time (min), mean (95%CI)	99.4 ± 34.7	
Hospital stay (days), median (min, max)	3 (2–4)	
Complications during surgery (n = 77), n (%)	1 (1.2)	Clavien-Dindo classification
Bladder injury	1	Grade 2
Complications during admission (n = 77), n (%)	16 (20.8)	
Vaginal erosion	1	Grade 1
Vault haematoma	5	Grade 1
Urinary tract infection	3	Grade 2
Bladder retention	1	Grade 2
Vaginal wound infection (antibiotics)	3	Grade 2
Vaginal wound infection (vaginal drainage)	2	Grade 3a
Parametrial abscess (drained percutaneously)	1	Grade 3a
Complications after admission (n = 77), n (%)	13 (16.9)	
De novo stress urinary incontinence (SUI)	1	Grade 1
Urgency urinary incontinence	4	Grade 1
Vaginal vault prolapse (conservative treatment: pessary)	1	Grade 3a
Vaginal vault prolapse (surgical colposacropexy)	6	Grade 3b
Posterior compartment prolapse (posterior vaginal repair)	1	Grade 3b
Total complications (n = 77), n (%)	30 (39.0)	

ACR, anterior colporrhaphy; PCR, posterior colporrhaphy; TVH, transvaginal hysterectomy; ME, mesh excision

mean operative time was 99 min, but it was 64 min in a similar study [17]. We have to consider that surgery was performed by more than 15 different surgeons on our team, and 7 were Obstetrics and Gynaecology Registrars. When analysing intra- and postoperative complications, our rates were slightly higher than those reported by other authors [27].

Table 4. Comparison of effectiveness and adverse events from vaginal pessary or surgery for POP treatment

Effectiveness	Pessary	Surgery	p value, post-hoc power
Yes	76 (84.4%)	69 (89.6%)	0.115[b] 44.1%
No	14 (15.6%)	8 (10.4%)	
	90	77	
Adverse events[a]			
Grade 1	24/76 (31.6%)	11/77 (14.3%)	< 0.001[b] 99.8%
Grade 2	0	8/77 (10.4%)	
Grade 3	0	11/77 (14.3%)	
Total	24/76 (31.6%)	30/77 (39.0%)	

[a] Clavien-Dindo grade

[b] Continuity-corrected chi-square test

One of the focal points of our analysis was adverse effects in the conservative treatment and surgical groups using the Clavien-Dindo scale to compare the clinical relevance of the complications. Patients in the surgery group had a higher rate of adverse effects (39%) than those in the pessary group (31.6%), and the difference was statistically significant (p < 0.01). Although first-degree complications were more frequent in the pessary group (31.6%), all were easily treated, and we did not find any second- or third-degree complications in those patients. On the other hand, in the surgery group, 24.6% of patients had a second- or third-degree adverse event, and those patients required more invasive procedures, such as drainage of a parametrial abscess percutaneously or a second surgery for vault prolapse.

The extrusion of the pessary was classified as Clavien-Dindo grade III by some authors [17]. We disagree because if extrusion is the cause of discontinuation, the pessary is already recorded as treatment failure, affecting the effectiveness of the method. Therefore, we recorded it as an adverse event of Clavien-Dindo grade I.

Our results suggest that a ring pessary without support can be recommended as first-line treatment in patients with

advanced stages of POP. In our opinion, it seems reasonable, when dealing with two treatments of similar efficacy, to choose the one with less severe adverse effects.

The study limitations include that it is a single-centre, prospective study with progressive recruitment without a defined sample size for statistical power. It was not randomized, as patients were able to choose between the two treatment options, and the sample size was limited. We designed a prospective cohort study because it was not possible to perform an RCT in our clinical practice. Our limitations were 30 months as recruitment period, an elderly population with little culture to accept participating in randomized studies, and budget limitation since the recruitment of patients was done during a daily gynaecology clinic in a public hospital. Vaginal hysterectomies were performed by 15 different gynaecologists, which may be a confounding factor. Another limitation of our study is that we did not offer any uterine sparing technique if the surgical option was chosen.

Validated questionnaires were not used to assess subjective outcomes, and a cost review was not performed. Additional prospective, multicentre studies with large sample sizes and an RCT are needed.

Conclusions

The pessary is effective and has mild adverse events in non-hysterectomized, postmenopausal women with advanced POP. Currently, it should be considered the first line of treatment together with PFMT. The preference of the patients must be considered at counselling. RCTs are needed.

Acknowledgements We thank all patients for agreeing to participate in this study.

Compliance with ethical standards

Conflicts of interest None.

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