Original Research

Vaginal Pessary in Women With Symptomatic Pelvic Organ Prolapse

A Randomized Controlled Trial

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OBJECTIVE: To compare pelvic floor symptoms, quality of life, and complications in women with symptomatic pelvic organ prolapse (POP) with or without vaginal pessaries in addition to those who do pelvic floor exercises for 12 months.

METHODS: This was a parallel-group, single-blind, randomized controlled trial with 12 months of follow-up. Women with symptomatic stage I to stage III POP were randomized to either pelvic floor exercises training (control group) or pelvic floor exercises training and insertion of a vaginal pessary (pessary group). The primary outcome was the change of prolapse symptoms and quality of life by using the Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaires. Secondary outcomes included bothersome of prolapse symptoms, desired treatment, and any complications.

RESULTS: From December 2011 through November 2014, 311 women were screened and 276 were randomized as follows: 137 to the control and 139 to the pessary group. One hundred thirty-two (95.0%) women in the pessary group and 128 (93.4%) in the control group completed the study. The Pelvic Organ Prolapse Distress Inventory of Pelvic Floor Distress Inventory and the Pelvic Organ Prolapse Impact Questionnaire of Pelvic Floor Impact Questionnaire scores decreased in both groups after 12 months, but the mean score differences were higher in the pessary group (Pelvic Organ Prolapse Distress Inventory: −29.7 compared with −4.7, $P<.01$; Pelvic Organ Prolapse Impact Questionnaire: −29.0 compared with 3.5, $P<.01$). Complication rates were low and similar in both groups.

CONCLUSION: We provided further evidence in nonsurgical treatment for POP. Prolapse symptoms and quality of life were improved in women using a vaginal pessary in addition to pelvic floor exercises.

CLINICAL TRIAL REGISTRATION: Centre for Clinical Research and Biostatistics–Clinical Trials Registry, https://www2.ccrb.cuhk.edu.hk/web/?page_id=746, ChiCTR-TRC-11001796.

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Pelvic organ prolapse (POP) affects approximately 50% of Swedish parous women older than 50 years of age.[1] In the United States, more than 226,000 women undergo POP surgery annually, and the direct costs of POP are estimated at more than $1 billion.[2] Various risk factors were identified for POP.[3–5] Women with POP have a variety of pelvic floor symptoms[6] and their quality of life was significantly impaired.[7,8]

Several options are available for treating POP.[9,10] Pelvic floor exercises were reported to be useful in 57% of women with mild prolapse.[11] One-to-one pelvic floor muscle training is effective for the improvement of prolapse symptoms.[12] Vaginal pessary is commonly used; 75% of specialist clinicians in United States offer this as the first-line therapy for their patients.[13] It can relieve their symptoms without taking surgical risks. However, Sarma et al[14] reported a high rate of complications in 56% of pessary users and the majority of women discontinue using a pessary. Only limited evidence is available on the use or effectiveness of vaginal pessaries; a high-quality study is needed to compare vaginal pessaries with other conservative treatment.[15,16]

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The aim of this study was to compare pelvic floor symptoms, quality of life, and complications in women with symptomatic POP with or without vaginal pessaries in addition to pelvic floor exercises for 12 months.

MATERIALS AND METHODS

This is a two-armed, single-blind, randomized controlled trial conducted in a tertiary urogynecology unit from December 2011 to November 2014 in women with symptomatic POP. Women who had dominant symptoms of prolapse and examined to have stage I to III POP using the pelvic organ prolapse quantification (POP-Q) system[17] with no previous treatment received were included. Exclusion criteria included active complications arising from the prolapse, impaired mobility, cognitive impairment, or language barrier. Enrolled women were randomized to either pelvic floor exercise training (control group) or pelvic floor exercise training and insertion of a vaginal pessary (pessary group). The procedures were in accordance with ethical standards of research and the Declaration of Helsinki. The study was approved by the Joint Chinese University of Hong Kong–Clinical Research Ethics Committee (CRE-2011.311-T).

Concealed randomization was performed with one-to-one ratio stratified in POP stage I or II and POP stage III by computer-generated random number series in serially numbered sealed envelopes. As a result of the nature of study, the treatment arm assignment could not be concealed from the women but it was concealed from the investigator who obtained the history and POP-Q findings from the women.

All eligible women completed the Pelvic Floor Distress Inventory and the Pelvic Floor Impact Questionnaire before the first consultation.[18] A visual analog scale (VAS) score was asked to describe the bothersome of their prolapse symptoms and their preferred treatment before the consultation. This information was concealed from the gynecologist and investigators. Demographic data, pelvic floor symptoms, and any complications were obtained using a standardized history sheet. Physical examination was performed using the POP-Q system. The study protocol was explained and they were randomized after written consent was obtained. A specialist gynecologist then assessed and inserted a vaginal ring pessary for women in the pessary group. The largest pessary that was comfortable for the women was used. If the vaginal pessary slipped out, reinsertion of same or next size of vaginal pessary was performed up to three times. A telephone hotline was given for both groups for early consultation if needed.

The waiting time for surgery in our unit was approximately 12 months. While awaiting surgery, women were able to participate in this study. A standardized pelvic floor exercise training course was offered to all women by registered nurse specialists who were trained as continence advisors. It included a teaching session within 2 weeks after the first consultation and three individual training sessions at 4, 8, and 16 weeks. They were advised to practice daily with at least two sets of 8–12 preset exercise repetitions per day, with 8–10 exercises per session at least two times per week. The regime was reinforced by continence advisors at every session.

Both groups received a phone consultation 2 weeks later. A successfully fitted vaginal pessary was defined as being able to be retained by the women who felt comfortable after 2 weeks. If the vaginal pessary slipped out, the women were offered a reassessment and replacement of the vaginal pessary. If a vaginal pessary was not able to be fitted, conservative management or surgery was discussed accordingly.

At the 6-month follow-up, both groups repeated the Pelvic Floor Distress Inventory, Pelvic Floor Impact Questionnaire, and VAS before the consultation. The subjective outcome was assessed by asking the women whether their condition was "improved," "the same," or "worse" since the first consultation. Compliance with pelvic floor exercise was reported by women. The vaginal pessary was removed in the pessary group before any assessment to achieve blinding. Their symptoms were reviewed and the POP-Q examination was repeated by an investigator from whom the intervention allocation was concealed. Women in the pessary group had the vaginal pessary reinserted by the first investigator who had originally removed the vaginal pessary. Estrogen cream was offered if there was a vaginal ulcer and a subsequent assessment was arranged for reinsertion of the pessary. If any complications arose from the pessary, the women were counseled for surgery or conservative management. Women in the control group received the same assessment except for the vaginal pessary replacement. Those who developed complications of prolapse were offered a vaginal pessary or surgery. The same assessment was repeated at 12 months. Their final desired treatments for POP were asked and they received the treatment accordingly after completion of the study.

Primary outcomes were the change in POP symptoms by using a validated Pelvic Floor Distress Inventory and the change in the quality of life by using the Pelvic Floor Impact Questionnaire at 6 months and 12 months after treatment. Both questionnaires use

a Likert scale with the higher scores representing more symptoms and bothersome.[19] A Chinese validated version was available and its responsiveness had been confirmed.[18,20] Secondary outcomes included the discomfort of prolapse symptoms measured by VAS score[21] and the desired treatment for the prolapse in the first consultation before any intervention and at the 12-month follow-up. Any complications and associated urinary symptoms that arose from both groups were documented.

The sample size was calculated from our observational study. We observed a score difference of 38.2 (standard deviation 58.0) in the POP domain of the Pelvic Floor Distress Inventory and 46.9 (standard deviation 86.1) in the POP domain of the Pelvic Floor Impact Questionnaire for women who received a vaginal pessary.[20] Assuming a difference of 20 in both scores between the two groups at the 1-year follow-up, with a standard deviation of 50, expected 20% dropout rate, 5% significant level, and 0.80 power, 120 women in each group were needed.

Data were analyzed using SPSS 22. Descriptive statistics were used for demographic data. Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire scores were tested for normality and median scores were reported. The primary outcome was analyzed at an intention-to-treat basis of all randomized women. Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire scores were compared between the baseline and 12 months by a multiple linear regression model. A square root transformation was used to obtain a normal distribution of the scores. Any missing value was imputed by a multiple imputation model, which was generated for each subscale score by performing a multiple linear regression in which the squared subscale score was the dependent variable and age, body mass index (BMI, calculated as weight [kg]/[height (m)]^2), parity, and compliance of pelvic floor exercise were independent variables. Mean score difference between groups was analyzed by paired *t* test. A linear logistic regression analysis was used to assess the effect of different factors on subjective improvement.

RESULTS

The trial profile is shown in Figure 1. In all, 276 eligible women were randomized to the pessary group (n=139) or the control group (n=137). At 12 months, there were 132 (95.0%) and 128 (93.4%) completed questionnaires in the pessary group and the control group, respectively. The baseline demographics were similar for both groups with the mean age being 62.6 (9.6) years, BMI 25.4 (3.9), and median parity of three.[2,3] Two hundred seventeen (79%) were postmenopausal and 176 (63.8%) of the women were sexually inactive. The anterior compartment was the most severe prolapse compartment and there was no significant difference in the baseline Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire scores (Table 1).

In the pessary group, 92 of 139 (66%) women were successfully fitted with a vaginal pessary and were comfortable (with no complaint of any complications and willing to continue with the pessary) at 2 weeks, 87 of 139 (63%) of them kept the pessary in situ at the 6-month follow-up, and 83 of 139 (60%) at 12 months. In the control group, 129 of 137 (94%) women were comfortable at 6 months and 120 of 137 (88%) remained on the conservative treatment at 12 months. Pelvic floor exercise was taught to all women in both groups. In all, 53 of 135 (39.2%) in the pessary group and 66 of 134 (49.3%) in the control group were reported to perform regular pelvic floor exercise at least two times a day and 3 days a week at 6-month follow-up and 56 of 130 (43.1%) in the control group and 72 of 135 (53.3%) in the pessary group at 12 months. There was no significant difference between the two groups (P=.10 and P=.10 at 6 and 12 months, respectively).

The median scores of the Pelvic Floor Distress Inventory and the Pelvic Floor Impact Questionnaire are shown in Table 2. The Pelvic Floor Distress Inventory–Pelvic Organ Prolapse Distress Inventory scores were significantly different between the two groups at 6 months and 12 months, and the Pelvic Floor Impact Questionnaire–Pelvic Organ Prolapse Impact Questionnaire scores were significantly different at 12 months. A multiple linear regression model was conducted to compare the Pelvic Floor Distress Inventory–Pelvic Organ Prolapse Distress Inventory and Pelvic Floor Impact Questionnaire–Pelvic Organ Prolapse Impact Questionnaire scores at the baseline and 12 months between the two groups. There was no interaction between the baseline scores and the treatment arm. The baseline scores and treatment arms were the only significant independent variables shown in the model. The mean difference of Pelvic Organ Prolapse Distress Inventory and Pelvic Organ Prolapse Impact Questionnaire score from baseline to 12 months was significantly higher in the pessary group when compared with the control group (Pelvic Organ Prolapse Distress Inventory: −29.7 compared with −4.7, P<.01; Pelvic Organ Prolapse Impact Questionnaire: −29.0 compared with 3.5, P<.01). The mean score differences of the Pelvic Organ Prolapse Distress Inventory and Pelvic Organ Prolapse

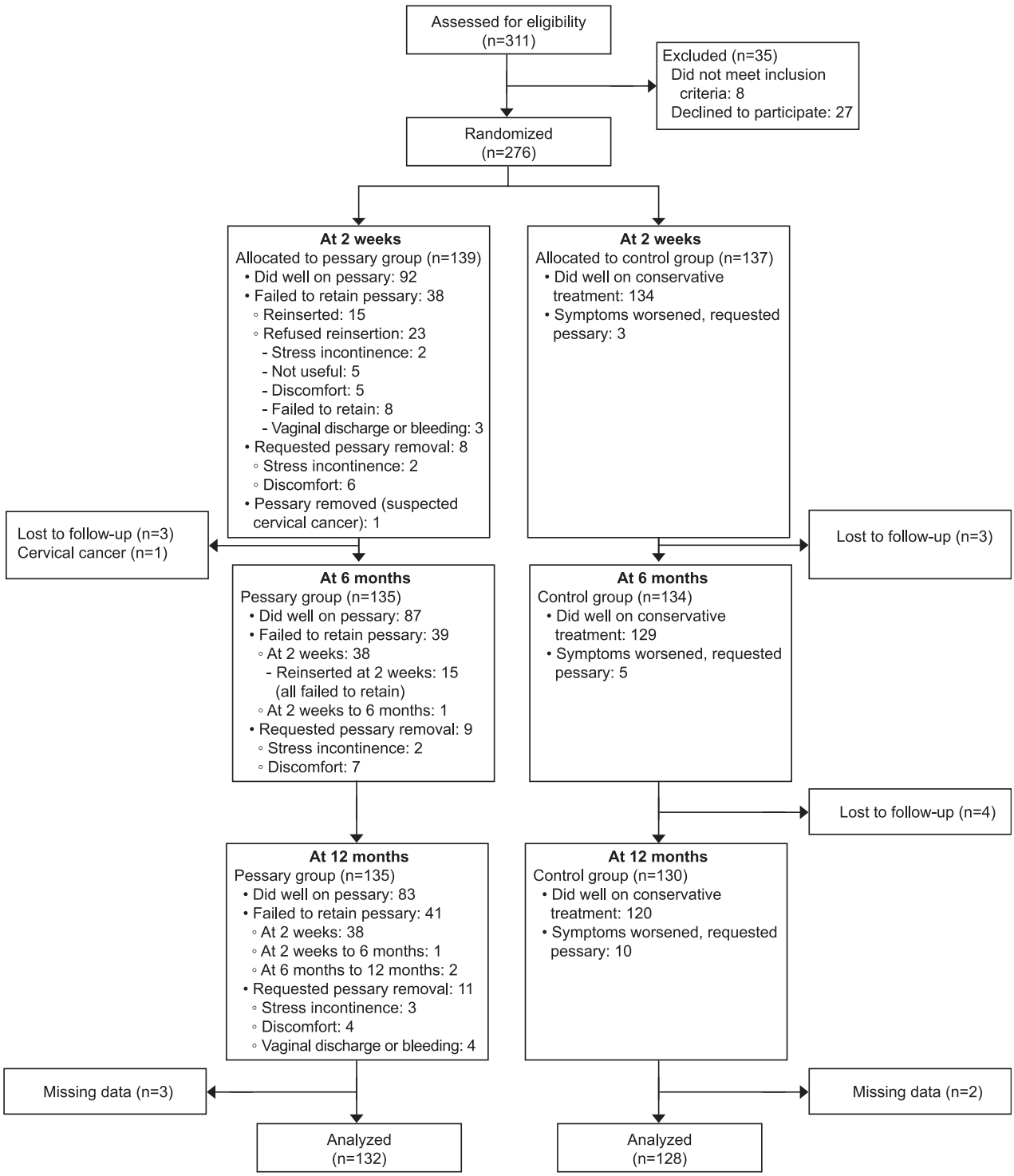

Fig. 1. Trial profile.
Cheung. Pessaries in Pelvic Organ Prolapse. Obstet Gynecol 2016.

Impact Questionnaire were also higher in the pessary group than the control group in stage I (Pelvic Organ Prolapse Distress Inventory: −21.6 compared with −6.0, P=.55 Pelvic Organ Prolapse Impact Questionnaire: −50.0 compared with −19.4, P=.29), stage II (Pelvic Organ Prolapse Distress Inventory: −25.2

Table 1. Baseline Characteristics of Study Participants

Characteristic	Pessary Group (n=139)	Control Group (n=137)
Age at recruitment (y)	62.5±9.1	62.7±10.2
BMI (kg/m^2)	25.6±3.8	25.1±3.9
Parity	3 (2–3)	3 (2–4)
No. of vaginal deliveries	2 (2–3.5)	3 (2–4)
Weight of biggest neonate delivered vaginally (kg)	3.3±0.5 (n=120)	3.3±0.6 (n=117)
Postmenopausal	112 (80.6)	105 (76.6)
History of hysterectomy	3 (2.2)	6 (4.4)
Sexually active	43 (33)	57 (43)
Stage of prolapse*		
I	11 (8)	14 (10)
II	96 (69)	92 (67)
III	32 (23)	31 (23)
Type of POP (most severe compartment)		
Anterior	90 (64.7)	91 (66.4)
Posterior	4 (2.9)	8 (5.8)
Apical	45 (32.4)	38 (27.7)
PFDI score		
POPDI	73.8 (39.2–118.5)	60.1 (25–101.2)
UDI	51.6 (36.0–87.5)	48.1 (22.8–80.6)
CRADI	44.5 (17.9–84.3)	41.1 (12.1–82.9)
PFIQ score		
POPIQ	25.8 (0–77.2)	16.6 (0–51.6)
UIQ	16.7 (0–63.9)	18.1 (0–53.0)
CRAIQ	0 (0–11.1)	0 (0–12.1)

BMI, body mass index; POP, pelvic organ prolapse; PFDI, Pelvic Floor Distress Inventory; POPDI, Pelvic Organ Prolapse Distress Inventory; UDI, Urinary Distress Inventory CRADI, Colorectal-anal Distress Inventory; PFIQ, Pelvic Floor Impact Questionnaire; POPIQ, Pelvic Organ Prolapse Impact Questionnaire; CRAIQ, Colorectal-anal Impact Questionnaire; UIQ, Urinary Impact Questionnaire.

Data are mean±standard deviation, median score (interquartile range), or n (%).

Stage of prolapse quantified by POP quantification stage of the compartment with most severe prolapse. All of these demographic and clinical characteristics were similar in the pessary and control groups, with no statistical difference ($P<.05$).

* Stage of prolapse defined according to POP quantification system.

compared with −7.9, $P=.02$; Pelvic Organ Prolapse Impact Questionnaire: −22.01 compared with 10.4, $P<.01$), and stage III (Pelvic Organ Prolapse Distress Inventory: −45.4 compared with 5.2, $P=.001$; Pelvic Organ Prolapse Impact Questionnaire: −41.9 compared with −4.2, $P=.03$) subgroup analysis. In the pessary group, more women achieved the minimal important difference in Pelvic Organ Prolapse Distress Inventory score than in the control group (86/139 [62%] compared with 48/137 [35%], $P<.01$) and more women also achieved the minimal important difference in Pelvic Organ Prolapse Impact Questionnaire score (49/139 [35%] compared with 23/137 [18%], $P=.01$).[20] The median scores of the Pelvic Organ Prolapse Distress Inventory and Pelvic Organ Prolapse Impact Questionnaire also were compared within the two groups. Pelvic Organ Prolapse Distress Inventory and Pelvic Organ Prolapse Impact Questionnaire scores in the pessary group decreased significantly at 6 months and 12 months when compared at baseline, whereas no significant difference was observed in the control group.

The median VAS scores decreased in the pessary group using the Friedman test (5.1, 4.6, and 4.7 at baseline, 6 months, and 12 months, respectively; $P=.001$), but there was no difference in the control group (4.9, 4.9, and 4.2 at baseline, 6 months, and 12 months, respectively; $P=.14$). More women in the pessary group reported prolapse symptoms as "improved" (80/132 [60.6%] compared with 36/128 [28.1%], $P<.001$). Logistic regression was performed to assess the effect of different factors including age, parity, BMI, stage and compartment of prolapse, menopausal status, sexual activity, with or without vaginal pessary, and the baseline Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire scores that may affect their subjective improvement. The only significant independent factor was the use of a vaginal pessary (odds ratio 5.3, 95% confidence interval 2.88–9.91, $P<.001$); others were all insignificant.

The complications and urinary symptoms in both groups are listed in Table 3. There was only one woman who had a vaginal infection, which was confirmed by the vaginal swab culture to be bacterial

Table 2. Pelvic Floor Distress Inventory and Pelvic Floor Impact Questionnaire Scores of Women at Baseline, 6 Months, and 12 Months

PFDI and PFIQ Subscales	Baseline	6 Mo	*P*	12 Mo	*P*
POPDI					
Pessary group (n=139)	73.8 (39.2–118.5)	40.7 (11.3–100)*	.02	32.1 (12.5–78.6)*	.04
Control group (n=137)	60.1 (25–101.2)	54.8 (22.6–103.6)		49.4 (21.4–95.2)	
UDI					
Pessary group	51.6 (36.0–87.5)	42.8 (21.0–81.3)	.87	39.4 (16.9–74.7)*	.57
Control group	48.1 (22.8–80.6)	41.0 (19.8–80.7)		37.5 (16.7–67.5)*	
CRADI					
Pessary group	44.5 (17.9–84.3)	42.3 (12.1–86.9)	.92	32.1 (15.8–75.5)	.80
Control group	41.1 (12.1–82.9)	40.6 (15.5–83.0)		32.1 (14.9–68.0)	
POPIQ					
Pessary group	25.8 (0–77.2)	5.6 (0–42.4)*	.22	0.3 (0–22.2)*	.02
Control group	16.6 (0–51.6)	8.3 (0–76.5)		8.9 (0–64.9)	.02
UIQ					
Pessary group	16.7 (0–63.9)	15.3 (1.6–48.6)	.33	13.3 (0–40.3)*	.71
Control group	18.1 (0–53.0)	11.1 (0–56.9)		9.7 (0–54.8)	.71
CRAIQ					
Pessary group	0 (0–11.1)	0 (0–5.6)	.90	0 (0–5.6)*	.77
Control group	0 (0–12.1)	0 (0–8.5)		0 (0–5.6)	.77

PFDI, Pelvic Floor Distress Inventory; PFIQ, Pelvic Floor Impact Questionnaire; POPDI, Pelvic Organ Prolapse Distress Inventory; UDI, Urinary Distress Inventory; CRADI, Colorectal-anal Distress Inventory; POPIQ, Pelvic Organ Prolapse Impact Questionnaire; UIQ, Urinary Impact Questionnaire; CRAIQ, Colorectal-anal Impact Questionnaire.

Data are median (interquartile range) unless otherwise specified.

Missing data generated from multiple imputation model (at 6 months, data missing for four patients in the pessary group and three in the control group; at 12 months, data missing for seven patients in the pessary group and nine in the control group were imputed).

P values refer to comparison of median scores between control group and pessary group by Mann-Whitney *U* test.

* Significant difference of median scores to the baseline scores within group by Wilcoxon signed-rank test ($P<.05$).

vaginosis and required antibiotic treatment in the pessary group. For de novo urinary symptoms, more women in the pessary group reported stress urinary incontinence, urge urinary incontinence, and voiding difficulty, but it only reached statistical significance for stress urinary incontinence. More women in the pessary group reported an improvement in voiding difficulties.

At the first consultation, only 88 (31.9%) women were able to indicate their preferred treatment; the majority of them had no preference. A total of 29 (10.5%) women preferred pelvic floor exercise only, 22 (8.0%) women preferred a vaginal pessary, and 37 (13.7%) of them wanted to have surgery. At the end of the study, all of the women understood the different treatment modalities; 63 (24.2%) preferred pelvic floor exercise, 55 (21.2%) preferred a vaginal pessary, and 142 (54.6%) opted for surgery. There were significantly more women in the pessary group who

Table 3. Complications and Urinary Symptoms in Women With and Without a Vaginal Pessary

Complication	Pessary Group	Control Group	*P*
Failed to retain pessary	56/132 (42.4)	—	
Abnormal vaginal bleeding	9/132 (6.8)	4/128 (3.1)	.17
Significant vaginal discharge*	6/132 (4.5)	2/128 (1.6)	.16
De novo urinary symptoms			
Stress urinary incontinence	24/50 (48.0)	13/58 (22.4)	.01
Urge urinary incontinence	17/73 (23.3)	19/84 (22.6)	.85
Voiding difficulty	10/92 (10.9)	8/97 (8.2)	.54
Improvement of pre-existing symptoms			
Stress urinary incontinence	19/82 (23.2)	15/70 (21.4)	.80
Urge urinary incontinence	17/59 (28.8)	18/44 (40.9)	.20
Voiding difficulty	25/40 (62.5)	11/31 (35.5)	.02

Data are n/N (%) unless otherwise specified.

* Significant defined as the discharge being unusual and bothersome.

preferred a vaginal pessary after 12 months than in the control group (28.0% compared with 14.1%, P=.01) and also more women preferred surgery in the pessary group (62.7% compared with 46.9%, P=.02).

DISCUSSION

Vaginal pessary can improve pelvic floor symptoms and also correct hydronephrosis in women with POP.[22–25] Nevertheless, whether these improvements vary in different staging of prolapse and how they weighed against the complications is still unknown. This study reported a significant improvement in prolapse symptoms in women with a vaginal pessary and pelvic floor exercise compared with those with pelvic floor exercise only. We published the estimated minimal important differences of the Pelvic Organ Prolapse Distress Inventory (−16) and Pelvic Organ Prolapse Impact Questionnaire (−29) scores in women who received a vaginal pessary after 1 year.[20] These score reductions were observed in a higher proportion of women in the pessary group. Subgroup analysis also confirmed the benefit of vaginal pessary in stage I to stage III POP. A vaginal pessary is therefore effective for different staging of POP and should not only be used in poor surgical candidates.

Current evidence of vaginal pessaries was mainly drawn from prospective studies.[15] Cundiff et al[26] reported a randomized crossover trial of a ring pessary and Gellhorn pessary for 3 months. It may be difficult to recruit women in a randomized controlled trial for a longer period of time. Our local health care system had favored the conduct of this randomized controlled trial with the long waiting time for operation here. Women were willing to have a vaginal pessary while waiting and this significantly contributed to our success in recruitment and a high follow-up rate.

We reported the complications in both the pessary group and control group. At 12 months, 58% of the women in the pessary group successfully retained the vaginal pessary, which is comparable with other reported figures.[14,26–28] Saram et al[14] reported the overall complication rate of 56%, which included pessary extrusion (28%), bleeding (47%), and vaginal discharge (26%). In this study, the extrusion rate was similar, but the vaginal bleeding (6.8%) rate was lower. This may be the result of the younger age of the women in our study. Interestingly, vaginal bleeding and discharge had a similar occurrence in the control group. This means that even without a vaginal pessary, POP itself may cause similar complications over time.

Clemons et al[22] reported 21% stress incontinence, 6% urge incontinence, and 4% voiding difficulty at 2 months after vaginal pessary insertion. We reported a higher rate of all these symptoms in the pessary group at 12 months, but the rates were also higher in the control group in de novo urge incontinence and voiding difficulty. This means, with the background risk of developing urinary symptoms, only de novo stress urinary incontinence would increase in women with a vaginal pessary. This may explain the higher proportion of women in the pessary group eventually choosing surgery.[8]

Currently, there is no standard recommendation on the timing to change the vaginal pessary.[29] The unexpected finding of low complication rates after 2 weeks of pessary insertion in this study also suggests 6-monthly replacement of the vaginal pessary is acceptable provided there are ways for women to consult a health professional if significant complications occur.

We aimed at a pragmatic study to recruit women who performed pelvic floor exercise in the control group. It would be unrealistic to have a pure control group who received watchful waiting only for an adequate follow-up period. Women may easily undertake pelvic floor exercise through other channels. With similar pelvic floor exercise compliance in both groups, an additional benefit of vaginal pessary was clearly shown.

There are several limitations in this study. We used a ring pessary but no other types of pessaries because it is the most commonly used in our center. Because there is no evidence showing that any type of pessary is superior to the others,[28] a single type was used to reduce any potential bias. Pelvic floor exercise was taught under our local protocol; the adherence rate was not very high compared with the reported figure,[30] but it was similar for both groups. At 12 months, a total of 61 women crossed groups with a different treatment being received by the allocated treatment arm. This reflects the actual clinical condition that we encountered everyday. We decided to measure quality-of-life scores as our primary outcome but not the anatomical outcome because the POP-Q assessment, which we made shortly after the removal of the vaginal pessary, may not be reliable. Furthermore, sexual symptoms were not reported because there is a lack of any validated questionnaires in our population.

We found a pragmatic study with adequate sample size and an excellent follow-up rate at 12 months. Women who had a vaginal pessary in addition to pelvic floor exercise had better improvement in prolapse symptoms and quality of life. We provide solid evidence to confirm a vaginal pessary is an effective treatment for women with different stages of POP.

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