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12 MONTHS OUTCOME OF WOMEN WITH SYMPTOMATIC PELVIC ORGAN PROLAPSE: VAGINAL RING PESSARY VERSUS CONSERVATIVE TREATMENT

Hypothesis / aims of study
Vaginal pessary has long been used for treating female pelvic organ prolapse. It is common, easy and safe to use. However, scare evidence was available for its use compared with conservative treatment (1).
This study compared the effects of vaginal ring pessary and conservative treatment on pelvic floor symptoms in symptomatic pelvic organ prolapse women.

Study design, materials and methods
This is a secondary analysis of a randomized controlled trial carried out in a tertiary urogynecology unit. Women were recruited from Nov 2011 to Nov 2013, with symptomatic pelvic organ prolapse (Stage I to Stage III) and received no previous treatment. They are randomized to have vaginal ring pessary or conservative treatment. Pelvic floor exercise was taught and encouraged in both groups. Secondary analysis was performed according to the final treatment received by the women. The outcome measure was the change in pelvic floor prolapse symptoms measured by validated quality of life questionnaires: Pelvic floor distress inventory (PFDI) and Pelvic floor impact questionnaire (PDIQ) before and 12 months after the treatment. Chi-square and student T-test were used and $p<0.05$ was considered statistical significant.

Results
276 women were recruited for the study, 137 of them were randomized for conservative treatment while 139 of them were randomized for vaginal pessary with similar baseline characteristics including age, parity, body mass index and stage of prolapse. After 12 months, 78 of them had successfully fitted with the vaginal pessary and kept for 12 months while 118 of them continued conservative treatment with pelvic floor exercise only and completed all follow-up. The compliance rate of pelvic floor exercise were similar in both groups (57.8% vs 47.7%, p=0.19), which was defined as regular pelvic floor exercise for at least 3 times a week and 2 times each day. The demographic of both groups was similar and listed in Table 1. There was no significant difference in all subscales of PFDI and PFIQ in conservative and vaginal pessary groups at baseline. After 12 months, all subscale scores of PFDI were significantly lower in vaginal pessary group than conservative group. For the PFIQ, all scores in conservative groups increased while there were significantly lower scores in pessary group (Table 2). 4(3.4%) women developed vaginal bleeding required topical hormonal treatment while 8 (10.2%) in conservative group. Another 3 (2.5%) had experience abnormal excessive vaginal discharge while 8 (10.2%) in conservative group.

Interpretation of results
Women with pelvic organ prolapse treated with vaginal pessary for 12 months showed significant improvement in all subscales in PFDI and PFIQ compared with women had pelvic floor exercise only. The side effects caused by the vaginal pessary including vaginal bleeding and abnormal vaginal discharge were not common.

Concluding message
Vaginal pessary is an effective treatment in treating pelvic organ prolapse compared with conservative treatment with pelvic floor exercise only. Women with vaginal pessary had lower scores in PFDI and PFIQ after 12 months and the associated vaginal bleeding and vaginal discharge were uncommon.

Conflict of interest: None.

Table 1. Demographic data of women in conservative group and vaginal pessary group

	Conservative group n=120	Vaginal pessary group n=78	p-value
Age (year)	62.2 (10.0)	64.6 (9.4)	0.31
Body mass index (kg/m^2)	25.1 (4.1)	25.4 (3.7)	0.60
Menopaused	93 (77.5%)	65 (83.3%)	0.32
Parity	3.1 (1.5)	3.0 (1.6)	0.71
Number of vaginal birth	3.1 (1.5)	3.0 (1.7)	0.77
Stage of prolapse - I/ II	91 (75.8%)	64 (82.1%)	0.30
- III	29 (24.2%)	14 (17.9%)	
Vaginal vault prolapse	9 (5.3%)	0	0.03
Most severe compartment of prolapse			0.80
-anterior	78 (65.0%)	53 (67.9%)	
- apical	35 (29.2%)	22 (28.2%)	
- posterior	7 (5.8%)	3 (3.8%)	

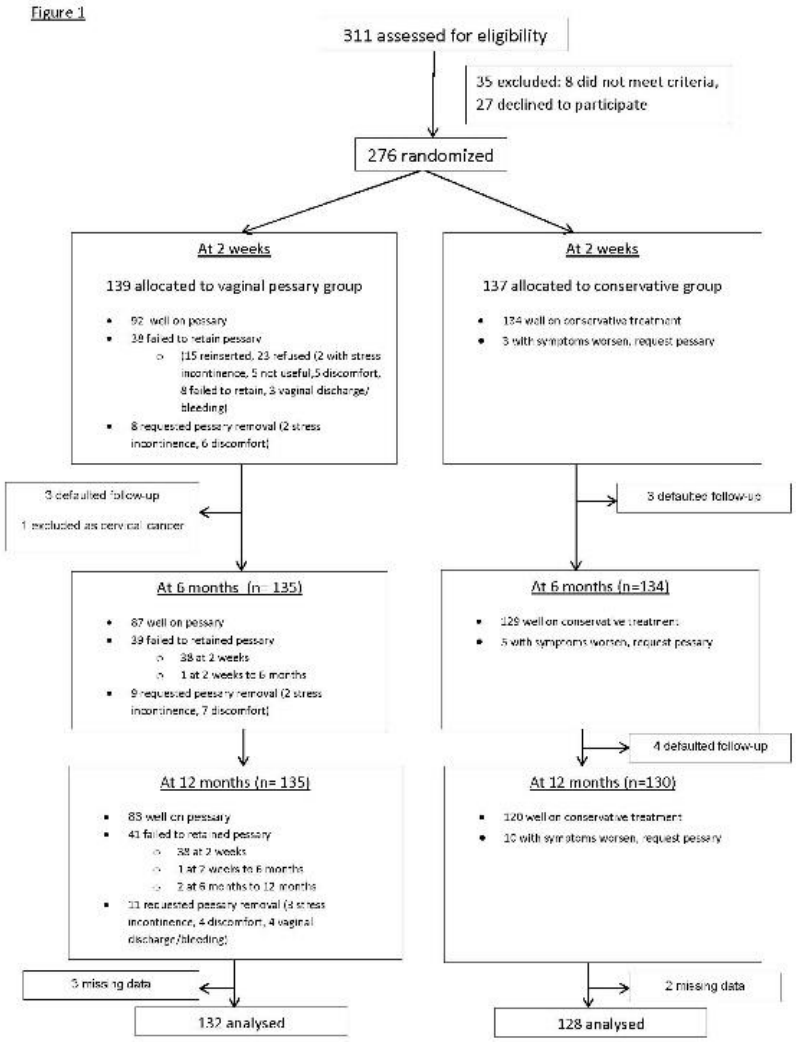
Data presented in mean (standard deviation) or number (percentage)

Table 2. PFDI and PFIQ scores of women with pelvic organ prolapse before and at 12 months after treatment received.

		Conservative (n=118)	Vaginal pessary(n=78)	p-value
PFDI				
POPDI	Before treatment	71.9 (56.8)	76.6 (58.0)	0.58
	12 months	68.2 (60.8)	30.7 (38.5)	<0.001
UDI	Before treatment	56.0 (45.2)	58.9 (42.8)	0.65
	12 months	51.5 (45.5)	38.0 (35.5)	0.02
CRADI	Before treatment	54.7 (50.4)	53.6 (52.5)	0.88
	12 months	53.8 (54.4)	38.4 (42.7)	0.03
PFIQ				
POPIQ	Before treatment	37.6 (54.0)	54.7 (67.2)	0.06
	12 months	45.4 (71.8)	11.3 (38.2)	<0.001
UIQ	Before treatment	39.9 (56.2)	38.9 (61.9)	0.91
	12 months	47.7 (76.9)	22.6 (40.1)	0.003
CRAIQ	Before treatment	16.1 (33.8)	16.5 (42.0)	0.94
	12 months	20.0 (58.7)	6.7 (27.1)	0.03

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, UIQ= Urinary Impact Questionnaire, CRAIQ= Colorectal-anal Impact Questionnaire.

Figure 1



References

1. Pessaries (mechanical devices) for pelvic organ prolapse in women. Cochrane Database Syste Rev. 2013 Feb

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Registration No.: CUHK_CCT00302 **RCT:** Yes **Subjects:** HUMAN **Ethics Committee:** Joint Chinese University of Hong Kong - New Territories East Cluster Clinical Research Ethics Committee **Helsinki:** Yes **Informed Consent:** Yes