

CHANGES IN URINARY SYMPTOM IN WOMEN TREATED WITH VAGINAL PESSARY WITH SYMPTOMATIC PELVIC ORGAN PROLAPSE - A RANDOMIZED CONTROLLED TRIAL

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, scarce evidence was available concerning its effect on urinary symptoms (1). This study aims to compare the effects of vaginal ring pessary and conservative treatment on urinary symptoms in symptomatic pelvic organ prolapse women.

Study design, materials and methods

This is a parallel randomized controlled trial carried out in a tertiary urogynecology unit with Clinical Trial Registry registered. Women were recruited from Nov 2011 to Nov 2013, with symptomatic pelvic organ prolapse (Stage I to Stage III) and received no previous treatment. Exclusion criteria included complications arise from the prolapse, e.g. confirmed retention of urine or presence of vaginal erosion or ulcer at consultation required active treatment for the prolapse problems, impaired mobility, cognitive impairment or language barrier that cannot complete questionnaires. They are randomized to have vaginal ring pessary or conservative treatment. Outcome measure included the change of urinary symptoms measured by validated quality of life questionnaires: Pelvic floor distress inventory-Urinary Distress Inventory (PFDI-UDI) before, 6 months and 12 months after the treatment.

Results

311 women were approached with 276 of them were recruited for study. Among the 276 women, 137 of them were randomized for conservative treatment while 139 of them were randomized for vaginal pessary and 260 (94.2%) of them completed all follow-up (Figure 1). Due to the nature of study, the treatment arm assignment could not be blinded to patient but it was blinded to the investigator who obtained history and POPQ finding from patients. The demographic of both groups was similar including age (62.5 in conservative group, 62.7 in pessary group), parity, Body mass index and stage of prolapse. Statistical analysis by intention to treat method using Friedman Test indicated there is significant improvement of PFDI-UDI total scores in both vaginal pessary groups and conservative groups (Table 1). Further using ANCOVA analysis after data transformation, there was no difference of the total scores between 2 groups. Clinically, the prevalence of co-existing stress incontinence, urge incontinence and voiding difficulty were the same in both groups after 12 months (Table 2). The de novo stress incontinence (24 vs 13, $p=0.06$), de novo urge incontinence (17 vs 9, $p=0.65$) and de novo voiding difficulty (10 vs 8, $p=0.67$) were similar in both groups.

Interpretation of results

Urinary symptoms in women with pelvic organ prolapse were improved similarly for those with vaginal pessary or on pelvic floor exercise only. There was no significant difference in the reported de novo urinary incontinence or voiding difficulty after using vaginal pessary.

Concluding message

Vaginal pessary is a common treatment for pelvic prolapse symptoms. Although pessary has reported to improve co-existing stress incontinence, urge incontinence and voiding difficulty (2), but compared with conservative group, the improvement was not significantly different at 12 months. Again the reported association of de novo stress incontinence, urge incontinence and voiding difficulty were with no difference to conservative group.

Conflict of interest: None.

Figure 1

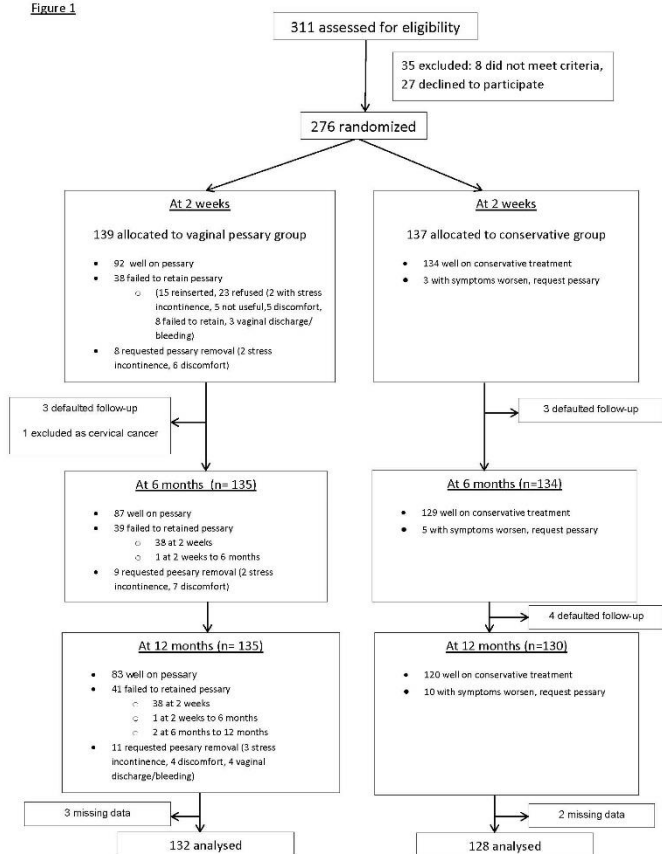


Table 1. PFDI-UDI scores of women pelvic organ prolapse before, at 6 months and at 12 months after treatment received by intention to treat analysis.

		Before treatment	6 months	12 months	p-value
PFDI-UDI-total	Conservative N= 128	54.8 (44.2)	56.1 (48.0)	49.6 (45.0)	0.032
	vaginal pessary N=132	65.5 (46.4)	58.0 (50.7)	52.9 (48.5)	0.004
obstructive	Conservative	22.4 (17.0)	22.6 (19.2)	21.0 (19.2)	0.36
	Ring	28.5 (19.7)	18.2 (20.4)	16.3 (18.7)	<0.001
irritative	Conservative	16.6 (15.9)	18.4 (17.6)	14.5 (15.6)	<0.001
	vaginal pessary	20.2 (16.3)	19.4 (17.6)	17.3 (16.5)	0.13
stress	Conservative	15.8 (19.4)	15.1 (18.5)	14.1 (17.6)	0.13
	vaginal pessary	16.9 (18.0)	20.4 (21.4)	19.3 (20.8)	0.11

Data presented in Mean(Standard deviation)

Table 2. Reported urinary symptoms in women in vaginal pessary group and conservative group.

	Before treatment			12 months follow-up			
	Vaginal pessary group N=139	Conservative group N=137	p-value	Vaginal pessary group N=132	Conservative group N=128	p-value	
Stress incontinence	86 (61.9%)	75 (54.7%)	0.23	81 (61.4%)	66 (51.6%)	0.11	
Urge incontinence	62 (44.6%)	46 (33.6%)	0.06	60 (45.5%)	42 (32.8%)	0.04	
Voiding difficulty	42 (30.2%)	34 (24.8%)	0.32	26 (19.7%)	29 (22.7%)	0.56	
				16 (12.1%)	21 (16.4%)	0.32	

References

1. Pessaries (mechanical devices) for pelvic organ prolapse in women. Cochrane Database Syst Rev. 2013
2. Patient satisfaction and changes in prolapse and urinary symptoms in women who were fitted successfully with a pessary for pelvic organ prolapse. Am J Obst Gyn 2004

Disclosures

Funding: None **Clinical Trial:** Yes **Registration Number:** The Centre for Clinical Research and Biostatistics, Clinical Trials Registry (CCTCTR); Registration number: 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