Does an early postpartum pessary treatment lead to remission of pelvic organ prolapse after vaginal birth? A pilot study

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INTRODUCTION

Stage II pelvic organ prolapse has been reported to be present in one third of women 6 weeks postpartum (1) and 29% of women described prolapse symptoms one year postpartum (pp, 2).

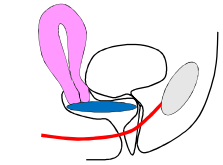
OBJECTIVES

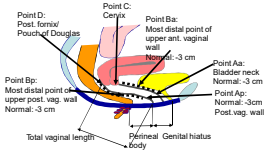
The aim of this study was to assess whether an early ring pessary treatment might reduce pelvic organ prolapse (POP) 6 weeks and one year pp compared to standard care.

METHODS

This study was designed as a randomised controlled trial

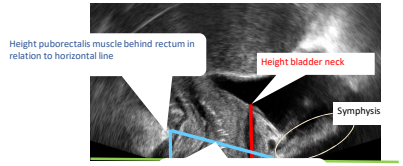
- women 1-2 days after vaginal birth with stage 2 POP
- vaginal ring pessary for 4 weeks or standard care (no interventions for 6 weeks pp)
- If women declined randomization, preference groups were established for both study arms
- PC-generated randomisation list, stratified for vacuum deliveries and levator avulsion, held by the study nurse. Allocation was placed in opaque envelops and opened after informed written consent had been obtained
- Blinding of women was considered impossible. Post-intervention assessors were blinded
- Exclusion criteria: Severe diseases of mother and/or child; previous pelvic floor operations; neurological diseases; severe perineal postpartum pain, high vaginal tears
- Recruitment of women: during pregnancy if possible or after vaginal birth

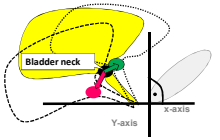




Assessment:

- Vaginal examination for levator avulsion
- Perineal ultrasound: bladder neck and puborectalis position at rest, during straining and pelvic floor muscle contraction (PFMC) supine and standing
- Examination at 6 weeks and 12 months postpartum
  → perineal ultrasound
  → POPQ
  → German version of Australian Pelvic floor Questionnaire (PFQ), modified and validated for use in pregnant and pp women (2)
- Power calculation: To demonstrate a clinically significant reduction of POP symptoms by half in comparison to the published prevalence of 29% of POP symptoms one year after vaginal birth with a power of 80% and alpha of 5%, 126 women are required in each group. An interim analysis was planned after six weeks: To demonstrate a clinically significant reduction of POP of 20% in comparison to the published prevalence of 39% of POP stage II after vaginal birth with a Power of 80% and alpha of 5%, 42 women are required in each group.





RESULTS

- 124 women were approached and 44 agreed to participate
- 17 women preferred standard care and 3 pessary insertion
- In 2/18 women planned pessary placement was impossible because of pain or it fell out. These two women continued in the standard group
- 2 women with reduced lochia and 1 with pain in the vagina → pessary removed
- In the standard group 10 women were lost for follow up, in the pessary group 3
- This study was stopped after one year because of slow and difficult recruitment as well as complications/pain.

Results as per treatment are summarized in the Table for randomised and preference groups together. Baseline demographic data were similar in both groups. There were no differences between groups regarding stress and urge urinary incontinence, anal incontinence and prolapse symptoms after 6 weeks or 12 months.

	Pessary group	Standard group	P
1-3 days post vaginal birth	N=16	N=28	
Age	31 (21-37)	30 (20-47)	0.509
BMI	25.3 (23.7-32.4)	27.4 (18.4-37.9)	0.253
Symphysis-PR distance	83.7 (63.0-92.7)	73.4 (64.0-102.0)	0.145
Bladder neck height	15.6 (5.5-25.6)	15.6 (-2 -29.5)	0.711
Transversal hiatal diameter	45.0 (33.0-69.1)	44.0 (34.3 – 51.8)	0.411
6 weeks postpartum	N=16	N=18	
Ba	-2 (-3 – 0)	-0.75 (-2 – 0)	0.042
Bp	-3 (-3 - -1)	-2 (-3 – 0)	0.365
PFQ Bladder score	0.83 (0-2.9)	1.0 (0-3.1)	0.857
PFQ Bowel score	1.6 (0.3-4.5)	1.3 (0-3.9)	0.756
PFQ POP score	0 (0-7.3)	0 (0-4.7)	0.987
PFQ Sex score	1.9 (0-7.4)	2.2 (0-3.0)	0.762
PFQ global score	3.7 (0.3-22.2)	3.6 (0-10.0)	0.883
Symphysis-PR distance	70.4 (55.7-83.5)	71.7 (48.9-83.5)	0.892
Bladder neck height	12.0 (0-16.2)	6.0 (-16.7 – 19.0)	0.041
Transversal hiatal diameter	43.1 (29.6-48.6)	42.3 (32.0-59.0)	0.872
12 months postpartum	N=13	N=18	
Ba	-1 (-3 - 0)	-1 (-3 – 2)	0.830
Bp	-3 (-3 - -2)	-1.5 (-2 – 0)	0.019
PFQ Bladder score	0.2 (0-3.3)	0.6 (0-1.9)	0.540
PFQ Bowel score	1.0 (0.3-2.9)	1.0 (0.3-3.2)	0.921
PFQ POP score	0 (0-8)	0 (0-2.7)	0.737
PFQ Sex score	0 (0-6.1)	0.9 (0-5.2)	0.680
PFQ global score	2.2 (0.5-20.3)	2.5 (0.3-8.6)	0.737
Symphysis-PR distance	67.0 (56.0-70.2)	62.1 (59.2-79.8)	0.662
Bladder neck height	15.9 (4.0-20)	18.1 (0-25.9)	0.792
Transversal hiatal diameter	41.3 (35.0-52.2)	44.5 (38.7-65.2)	0.548

Table:

6 weeks postpartum

- less anterior vaginal wall prolapse in the pessary group
- lower bladder neck position on straining in the standard group

12 months postpartum

- Less posterior vaginal wall prolapse in the pessary group

CONCLUSIONS

- Pessary treatment early after vaginal delivery seems feasible in symptomatic women and might reduce POP 6 weeks pp.
- It remains unclear why this benefit was not maintained after 12 months.
- This study was stopped prematurely because of slow recruitment and occasional pessary problems which were all solved with pessary removal.
- Results have to be interpreted with caution as the sample size was not reached.
- The results might well serve for future planning of trials.
- We consider the form of a ring pessary as insufficient and currently work on an anatomically more suitable form which must not constrict the cervix.

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