Early Vaginal Pessary as Secondary Prevention for Women at High Risk for Postpartum Pelvic Organ Prolapse: A Pilot Study

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BACKGROUND

- Pelvic Organ Prolapse is a major women`s health issue, especially during the postpartum period
- Currently the only known prevention method is pelvic floor physiotherapy

AIMS AND OBJECTIVES

- Our group aims to assess the acceptability and feasibility of using a specially designed irregular silicone hexagonal-shaped vaginal pessary [Conservative Pelvic Organ Pessary (C-POP)] in up to 10 postpartum women with high risk factors for pelvic organ prolapse for 12-weeks
- We hypothesize that the majority of women fitted with the C-POP will use it for the entire study period

METHODS

- Consecutive primigravid women who underwent either forceps or vacuum-assisted vaginal deliveries for >= term singletons with birthweights of >=3500g were invited to participate in this IRB-approved interventional observation pilot study
- Women who experienced 4th degree anal sphincter tears were ineligible
- The C-POP (Gynaecologic Pty Ltd., Melbourne, Vic, Australia) is available in 5 different sizes:
- XSmall [60mm(l) x 65mm(w)]
- Small [65mm(l) x 70mm(w)]
- Medium [70mm(l) x 75mm(w)]
- Large [75mm(l) x 80mm(w)]
- XLarge [80mm(l) x 85mm(w)]

Specify source of funding or grant:

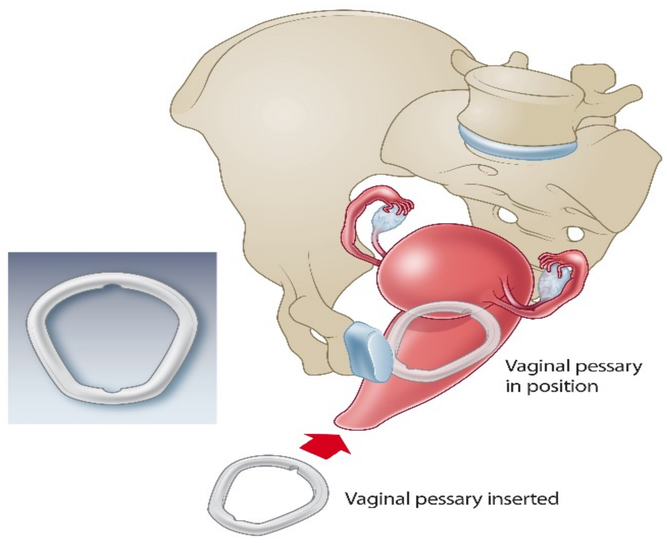
Epworth Healthcare.
Is this a clinical trial?
Yes.

Is this study registered in a public clinical trials registry?
Yes.

Specify Name of Public Registry, Registration Number:
Australian New Zealand Clinical Trials Registry (383871)

STUDY DESIGN

- Eligible women presented for their initial study visit 3-weeks postpartum, where they completed a clinical evaluation, questionnaires, and a physical examination. At this visit, women were then fitted with an appropriately sized novel flexible hexagonal medical grade silicone vaginal pessary determined on a ‘best-fit’ basis by the inserting clinician
- At two weeks after the initial fitting, women were reviewed and answered basic questionnaires
- At the final 12-week post pessary insertion visit, final questionnaires and clinical examinations including a prolapse assessment [pelvic organ prolapse quantification – POP-Q)] were completed
- This study is currently ongoing



CONCLUSIONS

- The high rate of pelvic organ prolapse highlights the need to develop secondary preventative strategies
- Using a vaginal pessary in the early postpartum period may reduce the prevalence of pelvic organ prolapse in at risk women
- This ongoing pilot study is an important first step in establishing the acceptability and tolerability of wearing a pessary postpartum before commencing a larger comparative study to assess the effectiveness and safety of using a pessary postpartum aimed at reducing the prevalence of pelvic organ prolapse

RESULTS

- A total of 43 eligible primiparous postpartum women were invited to participate, with three women (7%) officially enrolled.
- The mean age of all the women is 32.0 (+/- 4.1) years old, and that of the enrolled group is 34.0 (+/- 1.7) years old
- Average birth weights of the cohort was 3.9 (+/- 0.3) kg and that of the enrolled is 3.8 (+/- 0.3) kg
- Twenty-five women delivered with Neville Barnes forceps (NBFD) and 18 women had vacuum assisted vaginal deliveries (VAVD)
- Nearly all (95.3%) of the total cohort of women had a right mediolateral episiotomy including all of the enrolees
- The main reasons for declining to participate included concerns regarding perineal wound healing, fears of infection, and the unwillingness to attend appointments with a busy newborn
- The first officially enrolled (Enrolee 1) entered the study but withdrew on day 3 post C-POP insertion after experiencing an episode of vaginal bleeding which resolved after she removed the medium sized pessary herself. She was ultimately satisfied with the symptom resolution but became uncontactable thereafter
- Enrolee 2 and 3 attended all visits, no major issues or concerns raised.
- At the conclusion of the study, both remaining enrolees were ‘extremely satisfied’, would be happy to reconsider it if knowing using it could help prevent pelvic organ prolapse and they would recommend it to a friend.

REFRENCES

-Memon HU, Handa VL. Vaginal childbirth and pelvic floor disorders. Womens Health (Lond). 2013;9(3):265-77; quiz 76-7.
-Volloyhaug I, Morkved S, Salvesen O, Salvesen K. Pelvic organ prolapse and incontinence 15-23 years after first delivery: a cross-sectional study. BJOG : International journal of obstetrics and gynaecology. 2015;122(7):964-71.
-Memon HU, Blomquist JL, Dietz HP, Pierce CB, Weinstein MM, Handa VL. Comparison of levator ani muscle avulsion injury after forceps-assisted and vacuum-assisted vaginal childbirth. Obstetrics and gynecology. 2015;125(5):1080-7.