POMPOM 3-mo interim report: Nurse Practitioners in Women's Health (NPWH)

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TITLE:
POMPOM 3-mo Interim Report Measuring Effectiveness on Vaginismus and Dyspareunia Using a Novel Expanding Dilator

ABSTRACT

Purpose/Aim
This novel web-based observational study assesses the efficacy of an expandable dilator, in self-directed use, to resolve pain with heterosexual intercourse and treat vaginismus.

Methodology:
Milli expanding vaginal dilator purchasers joined a web-based study to investigate the efficacy of self-directed dilation therapy to achieve successful heterosexual intercourse. Participants signed an Informed Consent e-form, submitted answers to baseline questionnaire on demographics that included symptoms associated with dyspareunia (inability to have wanted vaginal penetration, sexual function, penetration pain), previous treatments, and experience with dilators. Subjects qualified for inclusion after confirming vaginismus meeting DSM-5 criteria for GPPPD and inability to achieve intercourse PEQ score of 0 ("not attempted") or 1 ("attempted but unsuccessful") on Item 1. For study inclusion, 74 qualified participants completed an initial use form, and 68 completed follow-up assessments 3 months after first use. Participants self-guided their use of the Milli expanding vaginal dilator using written instructions. No clinicians were involved.

At 3-months, subjects rated dilation therapy progress using validated questionnaires. Successful heterosexual intercourse was measured using PEQ Item 1 (successful penile insertion, scale of 0 = not attempted to 4=attempted, always successful). The Female Sexual Function Index (FSFI) provided a total score and subdomain scores—desire, arousal, lubrication, orgasm, satisfaction, and pain. Subjects rated anxiety with intercourse from 0 (no anxiety) to 10 (extreme anxiety). Subjects reported progress for return to intercourse and less painful sex goals.

Interim Results:
At 3 months compared to baseline:

- A statistically significant improvement was reported for Total PEQ ($p=0.0121$), FSFI ($p=0.0002$), Pain with intercourse ($p<0.0001$), and Anxiety ($p=0.0002$) with the percentage of patients reporting improvement 51.5%, 67.6%, 67.6%, and 57.4% respectively.
- 38.2% reported an improvement ≥1in PEQ-Q1 with an average improvement of 32.1%.
- 35.3% reported the ability to achieve intercourse (PEQ at least 2).
- 85.3% reported making progress toward or met their return to intercourse goal
- 75.0% reported making progress toward or met their less painful intercourse goal

Conclusion:
At the 3-month checkpoint, participants achieved statistically significant improvements in total PEQ, FSFI, Pain, and Anxiety with Intercourse and progress toward goals. These results support the effectiveness of an expanding dilator in treating vaginismus and dyspareunia.