POMPOM 3-mo interim Menopause sub-analysis for The Menopause Society

AUTHOR: Sheryl Kingsberg, Ph.D., University Hospitals Cleveland Medical Center

TITLE:
An interim menopause sub-analysis of the POMPOM study evaluating the efficacy of the Milli Expanding Dilator as a treatment for achieving intercourse

ABSTRACT

OBJECTIVE:
The primary objective is to evaluate the effectiveness of the Milli Vaginal Dilator in achieving full vaginal penetration with intercourse as reported on the Behavioral Functioning Primary Endpoint Questionnaire (PEQ) Question #1 (of ≥2).

METHODS:
The Milli vaginal dilator is a novel, FDA-cleared, expandable all-in-one tool that allows the user to increase the diameter in small increments before or once the device is inserted. The dilator also incorporates a vibration feature and provides an interface for tracking dilation progress.

Women who made an online purchase of the Milli vaginal dilator were invited to join an innovative, prospective, single-arm, longitudinal, web-based study. Inclusion criteria required subjects to meet the DSM-5 criteria for genito-pelvic pain/penetration disorder (GPPPD), specifically vaginismus, and a score of ≤1 (attempted but unsuccessful) on the Primary Endpoint Questionnaire (PEQ).

Demographic data included age, symptoms associated with dyspareunia, previous treatments, and experience with dilators. Enrolled qualified subjects (n=74) followed the Milli expanding vaginal dilator "instructions for use", dilating at home on a self-directed schedule (i.e., there was no healthcare professional guidance or intervention). After 3 months, subjects were prompted to report progress using validated measures: FSFI, PEQ, and Visual Analog Scale (VAS) Pain with Intercourse.

RESULTS:
For this 3-month sub-analysis, 68 participants (74 ITT-6 lost to follow-up) completed interim surveys. Participants were divided into two groups by age, 50+ (n=43) and <50 (n=25), for comparison. The 50+ cohort began with slightly lower PEQ, FSFI, and VAS Pain scores at baseline vs <50. All subjects improved on total FSFI and PEQ scores, VAS pain with intercourse, and reported making progress toward the primary goal of successful intercourse. Both groups reached similar maximum dilation diameters. Notable differences were observed in the 50+ cohort in the degree of improvement across 4 out of 6 FSFI subdomains. The 50+ (vs. <50) improved more on Arousal (25.9% vs. 16.9%), Lubrication (29.7% vs. 19.8%), Satisfaction (64.7% vs. 36.6%), and Pain (161.8% vs. 154.2%). No appreciable differences in improvement were reported in sub-domains of Desire and Orgasm between groups.

CONCLUSION:
After 3 months of self-directed Milli expanding vaginal dilator home use, participants demonstrated progress toward the primary goal of intercourse suggesting efficacy in the treatment of vaginismus using a self-guided intervention. Future studies can examine how expert clinician guidance might enhance improvements in the same time frame. Both groups reported reaching maximum dilation diameters that fall between static dilator sizes 6 and 7 (out of 8). Furthermore, the 50+ cohort showed greater improvements on 4 of 6 FSFI sub-domains vs the <50 cohort. Further investigation is warranted to better understand the potential reasons for this difference, such as higher treatment adherence or differing underlying causes of vaginismus (e.g., genitourinary syndrome of menopause) between age groups.

TABLE 1:

POMPOM 3-mo Interim Menopause Analysis(n=68)		
% with improvement from baseline	<50 (n=25)	50+ (n=43)
PEQ	48.0%	53.5%
Pain with Intercourse	72.0%	65.1%
Making progress toward/ returning to intercourse (goal)	84.0%	86.0%
Overall FSFI % improvement from baseline	72.0%	65.1%
FSFI Sub-Domains % improvement from baseline		
1-Desire	-3.5%	-2.7%
2-Arousal	16.9%	25.9%
3-Lubrication	19.8%	29.7%
4-Orgasm	25.3%	23.3%
5-Satisfaction	36.6%	64.7%
6-Pain	154.2%	161.8%
Reported Maximum Diameters Reached (Average)	32.9mm	32.2mm