Online Observational Clinical Trial for Assessing the Effectiveness of an FDA-Cleared Expanding Dilator

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Introduction:
Women are increasingly using the internet for self-diagnosis and treatment for medical problems. Vaginismus, a subset of genito-pelvic pain/penetration disorder (GPPPD), is a disabling condition associated with an inability to tolerate voluntary vaginal penetration, such as with tampons, intercourse/sexual penetration, or exams. Because of the stigma associated with this disorder, many women are reluctant to seek professional help and may benefit from web access to services. Little is known about women seeking on-line care for vaginismus and their experience through the healthcare system.

Objective:
To investigate the baseline characteristics and medical history of women self-diagnosed with vaginismus who are purchasing an expanding vaginal dilator online.

Methods:
Data was extracted from an on-line survey as part of an observational clinical trial for assessing the effectiveness of an FDA-cleared expanding dilator. Women purchasing the device through a commercial website completed a baseline questionnaire on gender, age, symptoms associated with penetration disorder, gender of sexual partners, sexual function, pain scores, and previous experience with healthcare professionals. Diagnosis of vaginismus was based on meeting the DSM-5 criteria for GPPPD. The severity of vaginismus was determined by use of the Lamont classification system, ranging from Grade 1 (able to relax for a pelvic exam) to Grade 4 (generalized retreat, buttocks lift up, thighs close). Participants indicated their average pain intensity during intercourse on a continuous scale from 0 (no pain at all) to 10 (extreme pain). Successful intercourse over the previous four weeks was measured by the degree of the partner's insertion, the first item of the Primary Endpoint Questionnaire (PEQ), scored on a Likert scale of 0 (not attempted) to 4 (attempted and always successful) . Given that the outcome measure of the PEQ is successful intercourse, only heterosexual women were recruited. Women with GPPPD were only included in the study if they had a score of ≤1 (attempted but unsuccessful) on PEQ Item 1. van Lankveld JJ. J Consult Clin Psychol. 2006 Feb;74(1):168-78.

Results:
Data from 74 participants were collected with a mean age of 51.0 years (range 18-77). The majority were nulliparous (58.1%). Prior to participation, 9.5% of participants had seen at least 2 healthcare providers for evaluation and treatment. Nearly two-thirds of the participants had reported symptoms associated with vaginismus for over 3 years, with 21.6% for 3-5 years and 43.2% for over 5 years. On the Lamont scoring system, 47.2% were Grade 1, 18.1% were Grade 2, 19.4% were Grade 3, and 15.3% were Grade 4 (two subjects did not provide a grade). A visceral reaction – extreme nervousness, palpitations, tremors, hyperventilation, sweating, and shaking – was reported by 32.4% of the participants. The mean total Female Sexual Function Index (FSFI) score was 13.5 (SD=7.4) and the mean VAS score during intercourse was 8.2 (SD=1.9).

Conclusions:
Women who self-diagnose vaginismus and purchase an expanding dilator using a web-based platform report significant limitations and discomfort associated with this disorder. Providing these women with an online option for accessing healthcare may help overcome barriers to diagnosis and treatment.

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