Vaginal Dilators: Issues and Answers

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ABSTRACT

Introduction: Vaginal dilators are often prescribed to facilitate an adaptive brain-body connection to decrease anxiety and pain that can be experienced in anticipation of sexual intercourse among populations of women with sexual pain syndromes. Postmenopausal women, cancer survivors, and women with a wide variety of pelvic floor disorders who experience genito-pelvic pain/penetration disorder (GPPPD) are often advised to incorporate vaginal dilators into their pelvic floor rehabilitation program and treatment regimens to enable penetrative intercourse with less pain. However, little is known about the behaviors of dilator users, what treatment protocols are most effective, how patients are currently using their dilators, and how effective are clinicians in helping their patients achieve success with their dilation therapy.

Methods: A recent PubMed literature search was performed using the key words vaginal dilator, vaginal dilator therapy, sexual quality of life, vaginal stenosis, vaginal dilation, vaginismus. A total of 29 English articles were reviewed and summarized. Articles were excluded for the following reasons: not in English and unrelated to dilator therapy.

Main Outcome Measure: This article will summarize the current research on vaginal dilators and discuss needs for future research to maximize patients' compliance and success with this treatment. Much of the summary data regarding user behavior will come from the early survey data with Milli, a novel, patient-controlled electronic dilator that slowly expands 1 mm at a time from its smallest diameter, 15 mm to a maximum diameter of 40 mm. Milli is currently being used by more than 1,000 women, and 3-month follow-up data were recorded on 335 of those patients.

Results: Dilators exist in multiple forms (plastic, latex, and medical grade material), may come individually or in sets, and many have special features such as vibration or the ability to be heated or cooled before use. Little is known about patients' use of dilators and the Milli's 3-month survey serves as an insight to patient dilator behavior. The most common medical goals for patients undergoing dilation treatment were return to penetrative intercourse and pain reduction during coitus. Patients were dilated on average 2.72 days/week; 56.8% of patients had suffered from sexual pain for 2 or more years and 36.3% had previously used static dilators. More than 70% of Milli users purchased Milli and are using Milli without the direct guidance of a clinician. The most common emotions patients used to describe their treatment were not only "anxious," "frustrated," but also "empowered" and "optimistic." The most common dilatory session duration was 6–10 minutes, mostly in the evening/bedtime (68.3%), located in the bedroom (96.8%). Adjunctive treatment included the following: vaginal moisturizers, local estrogen products, coital lubricants, and genital pelvic floor physical therapy. During the dilation sessions, women most often watched TV/videos, practiced mindfulness, or listened to soothing music. Factors that showed trends toward improved patient outcomes were length of dilation treatment (greater than 3 months) and use of meditation and soothing music. Factors not associated with improvement trends were as follows: when/where patients dilated and patient demographics including age, race, or religious preferences.

Conclusion: Patients who purchase dilators have often suffered with their condition for a long time and had difficulty finding a competent health-care clinician well versed in sexual pain syndromes that can help them. When patients did find a clinician, there were no clinically proven standardized protocols or formalized guidelines to give to patients about how to best use their dilators. Larger long-term interventions investigating a standardized dilation protocol are planned in future studies to better elucidate the effective and optimal dilation treatment plans. **Liu M, Juravic M, Mazza G, et al. Vaginal Dilators: Issues and Answers. Sex Med Rev 2020;XX:XXX–XXX.**

Key Words: Dilators; Sexual Pain; Pelvic Floor Hypertonus; Vaginal Dilation

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SCOPE OF THE PROBLEM

Data suggest that sexual pain, also referred to as genito-pelvic pain/penetration disorder (GPPPD), affects up to 34% of premenopausal women and up to 45% of postmenopausal women in the United States.[1] Defined in 2013 by the Diagnostic and Statistical Manual (DSM) of Mental Disorders, GPPPD includes the 2 previously comorbid diagnoses of dyspareunia and vaginismus.[2] A GPPPD diagnosis is made in a patient with clinically significant distress who has had persistent difficulty with vaginal penetration during intercourse, marked vulvovaginal or pelvic pain in anticipation of, during, or as a result of vaginal penetration, and/or marked tensing or tightening of the pelvic floor muscles during attempted vaginal penetration, with vaginal penetration referring also to instances such as tampon insertion or gynecological pelvic examinations.[1,2] Often, the pelvic/vaginal pain may start with a clearly defined medical condition including but not limited to pelvic floor muscle hypertonus, provoked vestibulodynia, vulvodynia, vulvovaginal atrophy, vaginal infection, dermatologic conditions (lichen sclerosus, lichen planus), neurologic conditions, previous trauma, scars, radiation- or radiotherapy-induced changes, hormonal variations, or pelvic organ adhesions.[2,3,4] It is common for the initial and underlying medical cause for the sexual pain during coitus to be effectively treated. Yet at times, pain may not be completely resolved, and a resultant diagnosis of GPPPD is made.[2,3] For other patients diagnosed with other pelvic conditions (ie, vaginismus or vulvodynia), no clearly defined physiological, biological, or medical etiology for the pain can be elucidated. Involuntary vaginal muscle contraction, hypertonicity of the levator ani muscles, must be treated in tandem with any other underlying medical conditions to effectively resolve GPPPD in the long term.[1,5] GPPPD causes significant personal, sexual, and marital distress for patients and their intimate partners.[1,5] Women with GPPPD often report higher levels of anxiety and depression, lowered self-esteem and body image concerns, as well as diminished desire and arousal.[1,5]

2 growing populations with GPPPD include women with malignancies and/or after their treatment and the postmenopausal women who has genitourinary syndrome of menopause (GSM). In 2016, it was estimated that there are approximately 8 million female cancer survivors, and, of those, 5 million women had either breast, uterine, or colon and rectal cancer.[6] One of the adverse effects of cancer treatment, especially with breast, uterine, and colorectal cancer, is dyspareunia—painful intercourse as a result of decline in estrogenic levels, impact on the vaginal mucosa and the resulting GSM. In a systematic review of 171 studies conducted worldwide, published between 2008 and 2015, two-thirds of the studies found that 29−64% of female patients with cancer (currently or previously) have experienced dyspareunia. Rates also trend higher for breast, gynecologic, and colorectal cancer, with reports of up to 45% of patients or more reporting GPPPD for breast cancer, and rates around 55% for gynecologic cancer and rectal cancer treated with radiotherapy.[7]

According to the recent census, 53 million women aged 50 years and older live in the United States. A woman is anticipated to spend approximately 30% of her lifetime in menopause, and as such, dyspareunia can represent a serious quality of life issue for this population.[8] A series of large-scale surveys have been conducted over the past 15 years to assess quality of life and incidence of vulvovaginal atrophy, a component of GSM, in menopausal women. These surveys have found that approximately 50% of menopausal women have vulvovaginal atrophy or vaginal discomfort, and of that subgroup, approximately 40% had self-reported dyspareunia or pelvic pain.[8,9] A 2012 study found that 72% of an estimated 13 million women who have pain with intercourse continue to engage in sexual intercourse at least once a month, and 34% of them have intercourse at least once a week despite their pain.[8]

A multidisciplinary approach can often be the most effective way to solve the complex issues that result in sexual pain. Cognitive behavioral therapy (CBT), mindfulness and relaxation training can address anxiety and fear. Pelvic floor physical therapy can be effective for addressing the taut muscles and spasm that often accompany sexual pain.[1,2] Other treatment modalities include intravaginal muscle relaxant suppositories, vaginal hormonal application, botulinum toxin injections, electromyographic biofeedback, electrical stimulation, manual tissue manipulation, stretching/strengthening exercises, and the use of pelvic dilators.[2]

Vaginal Dilators

Vaginal dilators are smooth, cylindrical devices (usually come in sets that are often progressive in diameter) that are inserted into a woman's vagina to facilitate stretching and relaxation of the underlying tissues.[10] Their use is supported by a variety of medical associations including the American Cancer Society, the National Forum of Gynecological Oncology Nurses, the North American Menopause Society, and the National Vulvodynia Association.[10−13] The therapeutic goals of vaginal dilation include providing stretch stimuli to gradually diminish fear and anxiety and promote pelvic floor muscle relaxation. This disrupts the painful cycle of hypersensitization and reflexive muscular tightening found in GPPPD.[1,2,10] Dilators also produce desensitization and provide a method of behavior modification.[11]

Static dilators progress from one designated size (length and diameter) to another and progress in a stepwise fashion. Low compliance with dilator therapy has remained a serious problem, with reported adherence rates as low as 25%.[10] A common reason stated by patients is that they experience pain and discomfort from dilator therapy, poorly defined intervention regimes and limited sizes of dilators, making shifting from one size to another cumbersome and confusing.[14]

Vaginal dilators are inserts with progressively larger diameters that are used to help stretch the vaginal lining and decrease pain. Here are some characteristics of some dilators.

Material

Dilators may be hard plastic, latex, silicone as well as glass. Material choice is related to patient preference as there is no evidence to support that one material is more effective or safer to use than another.

Sizes/Colors

Dilators come in a variety of colors and sizes. It is important to choose the sizes that best suit your patient's medical condition and underlying needs. Some may start at small or extra small sizes, and maximal diameters of dilator sets may vary.

Price Point

Dilators may be inexpensive to more than 200 USD dollars for a dilator or a set of dilators. Current evidence is lacking to support higher price points facilitating improved efficacy or safety; however, higher priced dilators may contain features that increase patient preferences.

Features

Dilators may have a variety of specific features. Some have vibration which some experts believe may decrease pain sensitivity or improve arousal and/or genital pelvic perfusion. Other dilators may have handles for easy manipulation, while others may be able to be heated or cooled.

Dilator Treatment Paradigm

There is no universally accepted treatment paradigm in terms of dilation paradigm. We currently do not know what the optimal frequency of dilation is (how often you should use your dilators in a week?) or duration of use (how long each dilation session should be?). Expert opinion suggests 3-5 times weekly at 10 mins per session may be optimal, but supportive data are lacking. Many sexuality professionals who prescribe dilators as a behavioral therapeutic intervention also encourage their patients to encourage mindfulness, watching television, or listening to soothing music during their exercises. There are no published scientific data to support that distraction is related to efficacy of dilation or time to successful penetration.

Recent data from a meta-analysis demonstrated that use of vaginal dilators had promising results for decreasing dyspareunia. "Idama and Pring[11] found complete relief from pain in 72% of participants as measured by an interview after home self-insertion treatments (N = 18).

Murina et al[15] studied the effect of adding dilators in 15 women with provoked vestibulodynia after one of the following treatments: electrical stimulation, vestibular infiltration, biofeedback, amitriptyline, or pregabalin. An overall treatment effect for pain intensity and sexual function was observed after treatment using validated outcomes. However, it is not possible to discriminate to the extent to which the dilators contributed to these changes."[16]

The literature does support that frequent follow-up visits to the health-care professional may help with patients' progress during dilation exercises. Patients should be encouraged to have frequent visits from their health-care professional who is well educated in sexual pain syndromes.

Some examples of commonly used dilators include the following:

Vagnismus.com (https://vaginismus.com/): These are static hard plastic dilators that come in a set of 6 different sequential dilator sizes. The dilators include a handle.

Soul Source Dilators (https://www.soulsource.com/): These silicone dilators come in 8 total dilator sizes, in a variety of colors, and can be purchased in sets of 4-5 dilators.

Berman Dilators (available on amazon.com): These hard plastic dilators only have 4 sizes; however, they may be the least expensive dilators and feature an optional vibrational feature.

She-ology wearable Dilators: The she-ology 5-piece silicone Wearable Vaginal Dilator is the first and only wearable silicone dilator set from CalExotics and Dr Sherry. It was specifically designed to provide more continuos dilation with your active lifestyle in mind.

Milli dilators: The Milli dilator is unique because it is patient controlled and expands electronically to size in increments of 1 mm from a baseline of 15 mm to 40 mm in diameter. It is one dilator that encompasses the diameter range of many commercially available dilator sets. It also has an optional vibration feature.

A summary of some of the most common vaginal dilators is included in Table 1.

BACKGROUND

Vaginal dilation is often recommended for women with GPPPD, for those undergoing radiation therapy, or for those who are diagnosed with GPPPD. Women with GPPPD can experience involuntary pelvic muscle contraction or spasm and feel overwhelming anticipatory anxiety that can lead to an avoidance of intimacy and sexual behavior. As a result, systematic desensitization involving progressive intravaginal dilation is often prescribed as an adjunctive therapeutic behavioral intervention.[17] Despite the popularity of systematic desensitization, there are very few randomized controlled trials assessing the success of dilator intervention. The development of a clinical program or randomized clinical trial which is placebo based may be difficult to create because the placebo arm may be watchful waiting without a medical or psychological intervention. Data concerning patient satisfaction with vaginal

Table 1. Characteristics of vaginal dilator

Name	Material	Sizes	Vibration	Special features
Soul Source	Silicone	12.7 - 41 mm - 8 different sizes, comes in set of 4	No	One specific for genital reassignment surgery (GRS) include: Rigid polyurethane
				Stable -49° to 158 degrees Fahrenheit. Maybe chilled or at room temp.
VuVatech	Silicone	12.7 - 38 mm - set of 5	No	Graduated dilators with and without Magnetics.
				Each vaginal dilator set contains over 60 Neodymium magnets.
Intimate Rose	Silicone	11.5 - 38 mm — set of 8	No	
She-Ology	Silicone	12.5 - 30 mm - set of 5	No	Wearable - small handle
Inspire	Silicone	12.5 - 32.5 mm - set of 5	No	
vaginismus.com	Hard plastic	15 - 38 mm - set of 6	No	Ergonomic solid-lock handle
	Medical-grade plastic			
	BPA, Latex, phthalate free			
Berman	Hard plastic	19 - 38 mm — set of 4	Yes	Has ribbed attachment and optional vibration
Syracuse	Hard plastic	13 - 35 mm - set of 7	No	
Amelie	Hard plastic	15 - 35 mm set of 5	No	
Cool Water Cones	Hydrocoloids	3 different cone sizes	No	Cone shaped, can be frozen, no lubricant needed
Milli	Silicone cover	15-40 mm expandable every mm	Yes	User can expand 1 mm at a time, optional vibration

dilation are also lacking. In the most recent and comprehensive Cochrane review on interventions for vaginismus, the authors ultimately found 5 articles that met their inclusion criteria.[17]

Van Lankveld et al,[18] the only randomized clinical study, evaluated the effectiveness of CBT administered in either group therapy or in bibliotherapy format and compared this with a wait-list control. Patients in the CBT treatment groups received a manual on the treatment of vaginismus, along with a CD-ROM with spoken instructions for relaxation techniques that were to be incorporated into their treatment paradigm. Treatment began with general relaxation techniques, followed by pelvic floor relaxation, followed by gradual exposure consisting of digital penetration, then dilation with a plastic dilator, and, finally, penile penetration. The results of the study showed that 14% of the total treatment participants (11 of 81) achieved penile-vaginal intercourse, compared with none of the participants in the wait-list control (9% group therapy, 18% bibliotherapy). These effects were maintained at 3-month and 12-month follow-up time periods. While this specific study does support the use of systematic desensitization for vaginismus, the authors, themselves, note that the small effect size may be problematic and limits generalizability and conclusions. They mention that this study warrants further investigation[18] using a larger sample size. Schnyder et al[19] used a quasi-randomization technique to allocate a total of 44 participants into 2 different forms of desensitization. In one group ("in vivo"), the physician advanced a vaginal dilator in a clinical setting, whereas in the second group ("in vitro"), the participant advanced her own dilator under verbal instruction by a physician. The patients were treated until pelvic symptoms resolved. After an average of 6.3 sessions, 43 participants (97.2%) were able to engage in intercourse and one-third noted an increase in sexual desire. There was no significant difference in treatment outcomes between the 2 groups. The results of this study suggest that vaginal dilation therapy (either in vivo or in vitro) can be successful in alleviating the symptoms of vaginismus, but superiority of one method vs another cannot be drawn because therapy continued until symptoms abated. It is also important to note, however, that both sexual desire and orgasmic capacity remained the same in 51.3% and 79.5% of the participants, respectively. Because there was no sham/or placebo control group, the small sample size of only 44 participants reduces the power of these results.[19]

In a study by Al-Sughayir,[20] a sample of 36 participants was alternately allocated to either systematic desensitization or hypnotherapy, and treatment was continued until satisfactory achievement of sexual intercourse. The researchers found that both behavior therapy and hypnotherapy were effective, although hypnotherapy was more effective at reducing sex-related anxiety. Because treatment was continued until symptom cessation and the completion of successful intercourse, it is difficult to draw conclusions on the superiority of one method vs the other.[20]

Finally, Zukerman et al[21] conducted a quasi-randomized trial of 60 patients, who were divided into 2 vaginismus treatment groups. The study group underwent the Paula Garburg sphincter muscle exercises for pelvic floor relaxation, along with gradual vaginal dilation using the Young vaginal dilators. The control group underwent the traditional Masters and Johnson desensitization approach along with the active introduction of Young vaginal dilators. Treatment was continued until successful intercourse was achieved or a number 6 Young vaginal dilator was able to be vaginally inserted. All participants, from both treatment arms, successfully completed the program. The average number of treatment sessions needed to achieve the desired outcome was shorter in the study group than that in the control group ($P < 0.001$). The authors concluded that pelvic floor relaxation exercises, combined with vaginal dilation therapy, is as or more effective than traditional behavioral therapy for vaginismus. However, because both groups underwent graduated vaginal dilation, the effect of vaginal dilation alone could not be ascertained.[21]

In an observational study by Murina et al,[15] 15 women with symptoms consistent with vulvodynia were instructed to undergo a graduated dilation therapy protocol for 8 weeks using the Amielle Comfort vaginal dilators. The Marinoff Dyspareunia Scale and Female Sexual Function Index scores were obtained before and after treatment. Both scores were significantly improved after vaginal dilator treatment.[15]

Cancer survivors are an important subgroup of patients who are often prescribed vaginal dilation. Currently, gynecologic cancers comprise the third most common malignancies in the United States. Improved screening, diagnosis coupled with treatment for early stage disease, has increased the number of women who are gynecologic cancer survivors. These women are at significant risk for sexual dysfunction and coital pain symdromes.[22] In a single survey, approximately, 47% gynecologic cancer survivors reported becoming sexually inactive after cancer treatment.[22] A cause of sexual dysfunction after treatment for gynecological cancers is vaginal stenosis, foreshortening, and fibrosis as a result of intravaginal brachytherapy or radiation treatment and/or surgically induced menopause, leading to severe GSM. Sequalae related to vaginal stenosis may include dyspareunia, painful insertion, tearing/papercuts at the vaginal introitus, and decreased overall sexual satisfaction. Women can also experience severe pain or difficulty with internal pelvic examinations which can ultimately adversely impact long-term cancer surveillance. A 2014 Cochrane review concluded that "Women who want to preserve the length of their vagina after radiotherapy should consider vaginal dilation. However, there are limited data from observational studies that suggest regular stretching of the vagina, once radiotherapy treatment is completed, might reduce the risk of scarring by a small amount."[23]

In the same year, a study was released describing risk factors for vaginal stenosis after brachytherapy for those patients who

had been diagnosed with endometrial cancer. Nonadherence was a statistically significant predictor of grade 2 or greater vaginal stenosis (odds ratio [OR]: 5.06, $P = 0.047$).[24] In a study by Hanlon et al,[25] patients with endometrial cancer treated with brachytherapy were prescribed a vaginal dilation regimen of 3 times weekly for 10 minutes. One group was randomized to receive nursing-directed education sessions, and the other received only standard institutional instruction. In comparison with the Law trial, adherence was only 20% of those who received specialized education continuing with prescribed treatment at 6 months, and 8% who did not receive nursing education.[25]

Bakker et al completed semi-structured interviews with 30 female patients who had been prescribed vaginal dilation after treatment for gynecologic cancer with external beam radiation therapy or brachytherapy. Reasons cited for nonadherence included the following: lack of time, privacy considerations, and general fatigue. Other factors impacting dilator use included negative emotions, hard plastic design of devices, anxiety, and an association of dilator use with its underlying malignancy and radiation treatment. Women reported using their dilators in the shower, with lubricants, and that smaller sizes with vibration as being helpful to ease of dilator use.[26]

The number of randomized controlled clinical trials assessing the effectiveness of use of graduated vaginal dilation for pelvic pain is sparse. The studies that do attempt to analyze vaginal dilation therapy use different methodologies and control groups, making it difficult to generalize across studies or conduct a meta-analysis. The number of subjects in each study arm remains small which is problematic. While the results of studies do suggest that vaginal dilators are an important part of GPPPD therapy, additional larger scale studies are needed to draw more definitive conclusions on their effectiveness and to ascertain patient satisfaction with their use.

METHODS FOR THE CURRENT ANALYSIS

An initial pilot study for the first expanding electronic vaginal dilator was completed to analyze various variables that lead to greater therapy success. Dilation protocols were not standardized and were at the discretion of the prescribing health-care professional. Currently, there are more than 1,000 women using the Milli dilator, and 3-month follow-up survey questionnaires were collected from 335 women. The surveys were divided into 4 sections: patient background, protocols, outcome measures, and general patient satisfaction. Patients were not given set universal direction in how to use or how often to use their Milli device, thereby leading to variation in usage depending on the patient's preference or clinician directives.

RESULTS

The detailed results and demographic information about race, age, and level of education of the study population are presented elsewhere. Most patients were educated Caucasian women. Age distribution was bimodal, at approximately 30 and 60 years of age. In addition, patients were asked about their experience with GPPPD, and many women reported having had difficulty receiving a diagnosis and treatment for their condition.

Most study subjects reported experiencing painful symptoms for an extended period of time (56.9% more than 1 year and 42.3% for 3 + years) before seeking medical help for their condition. The women saw multiple providers for treatment, with most seeing 3 or more clinicians to address their symptoms. (See table 2.) More than 40% of participants who reported frustration with dilation therapy (70.6%) had suffered symptoms for 3 or more years.

With the clinician's significant outreach efforts and minimal digital marketing, more than 70% of women (n = 1,000) were using Milli without the recommendation or guidance from a clinician. The data demonstrate that patients have been suffering from their condition for a considerable amount of time, patients have seen multiple clinicians, and many are using dilators without clinician involvement. Given these facets, it appears that clinicians may be remiss in counseling and recommending vaginal dilators as an adjunctive behavioral therapy for their patients.

The Milli Surveys ascertained that 92.9% used the dilator in their bedroom, and most frequent dilation times were completed either in the evening (28.3%) or before bedtime (40%). In addition, many patients used other adjunctive treatments with their dilation, with the most common being sexual lubricants (70%) and minimally absorbed local vaginal estrogen

Table 2. Patient experiences with clinicians

Variable	Category	Total (n = 123)
Duration patients have suffered with their condition	1 month	20 (16.3%)
	6 months	15 (12.2%)
	1 year	18 (14.6%)
	2 years	18 (14.6%)
	3–5 years	18 (14.6%)
	5 + years	34 (27.6%)
Number of seen clinicians	0	7 (5.7%)
	1	28 (22.8%)
	2	24 (19.5%)
	3	20 (16.3%)
	4	13 (10.6%)
	5+	27 (22.0%)
Time for patients to receive diagnosis	1 month	62 (50.4%)
	6 months	22 (17.9%)
	1 year	10 (8.1%)
	2 years	8 (6.5%)
	3–5 years	8 (6.5%)
	5 + years	10 (8.1%)

products (55%). Participants, who had a clinician, were asked how often their clinician instructed them to use Milli compared with how often they actually dilated. Similar to previous studies (published elsewhere), adherence with dilation regime was a challenge. A significant discrepancy between the prescribed number of uses and the actual number of times patients were using the dilator was identified. Some clinicians tended to instruct their patient to dilate 7 days per week, with the expectation (and understanding of inherent non-compliance) that patients would end up dilating 3-4 times per week. Patients reported that compliance varied owing to time of the day and home-life privacy constraints. (The average dilation frequency was approximately every other day.) Patient data were also analyzed based on diagnosed medical conditions, pain, and anxiety level at baseline (see Table 3).

Another factor evaluated was the frequency and time duration of each dilation session. Shorter periods of dilation time were the most popular, with 67% of women dilating for approximately 15 minutes or less. Patients who dilated for 11–15 minutes experienced the most consistent pain and anxiety reduction over time. Of note, patients who dilated for longer (16–30 minutes) experienced easier dilation sessions over time and yielded higher patient satisfaction. Patients who dilated between 16 and 20 minutes reported the highest anxiety and pain reductions. It appears that a 15-minute dilation episode is the optimal time for consistent pain and anxiety reduction, easier dilation sessions over time, and higher patient overall satisfaction.

The number of months that the patients used their dilator indicated a trend, demonstrating that the more months the dilator was used, the more successful the treatment was across all outcome measures (decreased pain, anxiety, and return to intercourse). The longer patients have undergone dilation treatment, the better their outcomes. Activities that seemed to distract the patient from their dilation therapy were popular, such as watching TV and reading which made up 31.3% of patient answers. Patients who read during dilation sessions reported some of the worst results, with less pain and anxiety reduction and little impact on ease of dilation. Patients who focused on deep breathing or relaxation techniques without distraction reported the largest pain and anxiety reduction.

The role of a patient's partner was also an area of research in the Milli Survey data. Those whose partners were aware of the patient's vaginal dilator (n = 17) and those whose partners were present in the room during the dilator session (n = 24) had higher pain reduction. Patients who used their dilator before intercourse showed the highest reduction in pain and anxiety. Those whose partners were present during use of Milli before intercourse had similar pain and anxiety reductions. Patient success was also assessed based by medical condition. There were no changes in pain or anxiety reduction based on a specific condition. The best treatment outcomes were observed in chronic pelvic pain, vaginismus, and vulvodynia patients; worse

Table 3. Patient conditions

Condition	Sample size	Avg. age	% Baseline sexually active	Avg. baseline pain at rest	Avg. baseline pain at intercourse	Avg. baseline anxiety	Sample size	Avg. days/week told to use	Avg. days/week actually used
ALL	132	47.26	43.94%	2.57	7.05	7.08	71	4.1	2.51
Vaginal dryness/VVA/GSM	68	55.76	45.59%	1.63	7.02	7.37	38	3.77	2.28
Post cancer	13	49.15	38.46%	2.5	7	7.33	9	4.44	2.67
Chronic pelvic pain	32	44.84	46.88%	3.62	7	6.78	13	4	2.69
Painful intercourse /dyspareunia	105	48.89	49.52%	2.54	7.03	6.91	58	3.95	2.55
Vaginismus	38	41.31	47.37%	2.92	7.41	7.04	22	4.82	2.64
Vulvodynia	37	40.94	43.24%	3.73	7	7.77	21	4.24	2.9
Vaginal stenosis	9	53.44	44.44%	1	8	7.38	5	4.75	1.25
Lichen sclerosus	17	54.81	58.82%	2	6.8	6.75	12	3.45	1.73
Pelvic floor hypertonus	21	43.76	47.62%	3.82	7.54	7.64	12	3.83	2.75
Anxiety, depression, or PTSD	40	46.61	45.00%	2.95	7.13	7.71	19	4.32	2.68
Other	21	48.24	38.10%	1.57	6.71	6.55	11	4.55	2.91

ALL = all conditions; GSM = genitourinary syndrome of menopause; PTSD = post traumatic stress disorders; VVA = vulvovaginal atrophy.

treatment outcomes were among women after cancer, with a diagnosis of lichen sclerosis.

DISCUSSION

Data analysis of the Milli pilot study data identified several predictors of patients' dilation results and success. The number of months that a patient dilates, in particular, had a noticeable trend indicating that pain and anxiety reduction, diameter gain, feelings of improvement (93.3%), and patient satisfaction improved as treatment length progressed. Patients suffering from more severe symptoms needed more time to improve and benefited from both dilation and adjuvant therapies. Women who dilated for at least 15 minutes per session showed lower anxiety and pain scores. The use of reading during dilation hindered progress, whereas relaxation techniques appeared to improve recovery. Partner presence during dilation and the use of dilators before coitus were associated with significant reduction in pain and anxiety levels.

The survey strengths included the ability to assess usage of dilators in multiple circumstances and may provide some insights regarding which factors may be associated with greater treatment success. The limitations of the survey included a small sample size considering there was a diverse and heterogenous patient population with many medical conditions for which dilators are used. The fact that the survey is a self-reported retrospective survey design also is a significant limitation. Multiple adjunctive medications that participants were taking certainly may also act as a confounder, as does the variability of health-care provider instructions for dilator use. Strength includes prospective design and multiple surveys completed over time.

CONCLUSION

Patients who purchase dilators have often suffered with their condition for a long time and had difficulty finding a competent and savvy health-care professional who can help them. Many women use dilators without the direct guidance of a medical clinician/counselor or physical therapist, and when patients did locate a provider, there were no standardized protocols or guidelines given to patients about how to best use their dilators to achieve success. Results from this survey suggest that the ideal dilation treatment routine includes a long-term commitment of over 3 months. This information may help patients set realistic goals and expectations for their treatment.

Future studies are needed to refine and compare specific dilator protocols, including duration and frequency of a dilation session, use of vibration, when to increase diameter, and other factors that improve patient outcomes. Between dilator studies, comparing different dilators is necessary to discern which type of dilator is best suited for a specific medical condition. Comparative prospective outcome trials of Milli dilation vs placebo arm of watchful waiting are warranted to further characterize dilation as an adjunctive treatment for GPPPD.

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