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Patient perceptions of vulvar vibration therapy for refractory vulvar pain

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The objective of this study was to describe acceptability of vulvar vibration therapy (VVT), a novel treatment approach to vulvodynia. We included women with vulvodynia who attended the Pelvic Pain Clinic and had used VVT for at least two weeks. Participants completed a three-page, 65-item, questionnaire assessing demographics, VVT usage and responses to Likert statements regarding accessibility, comfort and symptom response to VVT. Of 69 qualifying patients, results from 49 (72%) were eligible for analysis. Participants were primarily white, married and well-educated, with a median age of 30 (range 19–68 years). Median duration of vulvar pain and dyspareunia was two years (0–23) and three years (0–30), respectively. Median duration of VVT was five months (1–18) and three days per week (0.5–7). Fully, 83% said that, ''vibrator treatment is an acceptable treatment'', 83% said that they were ''satisfied with vibrator treatment'', 76% endorsed vibrator as comfortable to use, 73% indicated that sex is less painful since starting vibration treatment and 88% would recommend VVT to others. We conclude that the therapeutic rationale for VVT is based on the anti-nocioceptive properties of vibration and on the favorable response of vulvodynia to physical therapy. Vulvar vibration therapy is safe, inexpensive and, in this survey, acceptable to most patients, many of whom described improvement in symptoms.

Keywords: vulvodynia; physical therapy; vibration; vulvar vestibulitis; vestibulodynia; dyspareunia

Introduction

Vulvodynia, chronic vulvar pain of at least three months duration, is a complex disorder with poorly understood pathophysiology and non-specific treatment options. The syndrome is further complicated by an ever-changing terminology, having been referred to with such terms as ''vulvar vestibulitis syndrome'' and ''vestibulodynia''. We opted to use the currently accepted simplified term, ''vulvodynia'', rather than ''localized provoked vulvodynia'' in this manuscript (Haefner, 2007; Haefner et al., 2005). Our clinical diagnoses for women included in the study were based on Friedrich's (1987) clinical diagnostic criteria for what was termed ''vulvar vestibulitis'': severe pain on vestibular touch, entry dyspareunia, tenderness to pressure localized within the vestibule and physical findings limited to erythema of various degrees (Baggish & Miklos, 1995; Friedrich, 1987).

The exact prevalence of vulvodynia is unknown, but estimated in a National Institutes of Health (NIH) population-based study to be approximately 16% of the female population (Harlow & Stewart, 2003). The pain of vulvodynia may be present only during

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attempted coitus or also during other daily activities (e.g. sitting, walking and exercise). Repercussions include: sexual dysfunction; disruption of daily activities and relationships; and depression (Bachmann et al., 2006a). Frequent office visits and non-specific, expensive treatments make vulvodynia both an emotional and financial drain on the patient and the healthcare system (Harlow & Stewart, 2003).

Similar to other pain syndromes, vulvodynia presents with a broad spectrum of severity and response to therapy, likely reflecting a variety of etiologic factors. The absence of a single clearly culpable etiology complicates the search for a targeted therapy and is evidenced by the range of treatment options, including topical and injectable agents (steroids, lidocaine, capsaicin and estrogen), neuromodulators, such as tricyclic antidepressants, physical therapy or biofeedback and surgical removal of affected skin with advancement of vaginal mucosa (vestibulectomy) (Barbero et al., 1994; Bornstein, Pascal, & Abramovici, 1993; Traas et al., 2006). There is currently no gold standard for the treatment of vulvodynia, and, as for many pain syndromes, the ''ideal'' is probably a multi-modal approach.

Most treatments traditionally focused on skin sensitivity with some attention given to neural modulation. More recent theories and treatments add to our understanding by illuminating the role of pelvic floor myalgias (Bachmann et al., 2006b). The novel treatment we present below, which we have called ''Vulvar Vibration Therapy'' or VVT, was developed to target the myalgia component of vulvodynia with benefit from nerve conduction modification. Given that there is a significant muscular component as well as a somato-sensory component in vulvar vestibulitis (Glazer, Jantos, Hartmann, & Swencionis, 1998), we wanted to test whether a conventional therapy for myofacial pain might be useful. Vulvar vibration therapy consists of a vibratory stimulus and massage-like pressure applied daily to the vulva and nearby pelvic floor, with particular attention to areas of muscle tension and tenderness. Based on a modification of pelvic physical therapy techniques, this general approach, however, is supported by studies demonstrating improvement in chronic vulvar pain after physical therapy (e.g. massage, electromyographic biofeedback, electrical stimulation and home exercises) (Bergeron, Binik, Khalife, & Pagidas, 1997a; Bergeron, Bouchard, Fortier, Binik, & Khalife, 1997b; Bergeron et al., 2002; Glazer, 2000; Glazer, Rodke, Swencionis, Hertz, & Young, 1995; Rosenbaum, 2005). To our knowledge, there is no previously described use of vibratory stimulus for vulvodynia. Vibratory stimuli applied to other pain syndromes, however, have been shown to have an anti-nocioceptive effect, for instance, by decreasing the sensitivity of peripheral nociceptors (Lundeberg, 1983, 1984, 1985; Lundeberg, Ekblom, & Hansson, 1985). Furthermore, as a remedy applied to many female ailments (Sonksen, Ohl, Bonde, Laessoe, & McGuire, 2007) since the 1800's, use of a vibrator on the female genitalia would likely be viewed as familiar and safe and it is an inexpensive treatment amenable to self-administration in the home (Angier, 1999; Davis, 1996). Though not yet studied, we also theorized that use of vulvar vibration might also address some aspects of sexual dysfunction (such as secondary aversion to coitus and decreased libido) that can complicate vulvodynia (Brotto, Basson, & Gehring, 2003; Meana, Binik, Khalife, & Cohen, 1997; Reed et al., 2000).

Though our own patients have reported noticeable improvements in their pain and intercourse-related discomfort when their muscular tenderness is addressed in some way, we emphasize here and have emphasized to our patients that VVT is not supported by clinical trials and the effectiveness is therefore unknown. The following survey was not a study of effectiveness, but rather, was a pilot study to assess the usage patterns, acceptability and tolerability of VVT as perceived by the women who used it empirically for residual or refractory vulvodynia.

Methods

Approval for the study was obtained from the University of North Carolina Biomedical Institutional Review Board in accordance with the Helsinki Declaration of 1975, revised in 1983. This descriptive, questionnaire-based survey evaluated women who were seen for vulvodynia at the University of North Carolina Chronic Pelvic Pain Clinic between August 2004 and October 2005 and who used VVT as an empirically offered treatment. Only women who used VVT for vulvodynia for at least two weeks were eligible. We approached all eligible women during this time frame, by means of a phone call or at one of their office visits, offering participation.

Participants in this survey had presented with a diagnosis of vulvodynia, as described by Freidrich (1987) and were generally first treated with six to eight weeks of topical therapy (topical lidocaine, topical estradiol or lidocaine compounded with concentrated estradiol) (Zolnoun, Hartmann, & Steege, 2003). Most patients who had continued tenderness with residual muscular component were offered the opportunity to try VVT as a self-administered novel approach to their pain. Most of these patients purchased the physician-recommended, commercially available vibrator. This device has three vibration intensities and is characterized by a smooth bulb, 5 cm in diameter, situated on the end of a flexible neck (Figure 1). It is commercially available at

Figure 1. Evibra massager available at www.evibra.com and recommended by physicians at the UNC Chronic Pelvic Pain Clinic for VVT.

www.evibra.com under the product name "evibra massager". At the time of the study it cost patients approximately $25. Based on our experience with previous patients, we suggested during our ten-minute pre-treatment supervised instruction in the clinic that patients apply the vibratory stimulus primarily to tender muscular areas of the distal pelvic floor for five to ten minutes each day. During a ten-minute pre-treatment supervised instruction in the clinic, we suggested five to ten minutes of VVT daily based on our experience with previous patients and applying the vibratory stimulus primarily to tender muscular areas of the distal pelvic floor. Patients were taught to identify areas to treat by tenderness to deep digital palpation, generally located at the five and seven o'clock position just inside the hymenal ring. We also recommended using the bulb on the end of the device to achieve a gentle stretch of the muscles of the introitus. Patients were instructed to use any type of lubrication that did not irritate them. For patients with severe dyspareunia, we suggested that they apply the vibrator over the perineum initially, gradually work towards insertion over a period of 4–6 weeks and use VVT prior to intercourse. All patients achieved insertion of the device.

If consent was obtained for participation, we mailed our questionnaire. If the questionnaire was not returned within two weeks, subjects were contacted by phone to request return of the questionnaire. Up to three phone calls were made and no additional incentives were offered. Eight questionnaires were re-mailed when requested by participants. Two trained research assistants abstracted data from the questionnaires. Data abstraction was then duplicated to ensure accuracy.

The survey tool was a three-page, 65-item original questionnaire that required 10 minutes to complete. The first part of the questionnaire collected demographic data, duration of symptoms, current and past treatments and details of the VVT (e.g. duration of use, type of device and preferred vibration frequency). The second half was a series of statements aimed at evaluating the constructs of accessibility, acceptability and perceived effectiveness of VVT. Responses were formatted as a Likert scale with options ranging from 1 (strongly disagree) to 4 (strongly agree), with no available neutral response. Examples of typical statements were: "This treatment was embarrassing" or "The appearance of the device was professional".

All statistical analysis was performed with the statistical program, Stata 9.1 (College Station, TX). We performed primarily a univariable descriptive analysis. Missing variables ranged from 0–8 (of 49 total) for the different items, with the most common missing response being to the Likert questions: "VVT makes sex more enjoyable" (seven missing) and "Sex is less painful since I started vibrator treatment" (eight missing). There was no clear pattern of missing variables by subject characteristic; we did not impute missing variables.

We examined Pearson's correlations between similar items in the Likert statements to assess internal validity of the questionnaire. Responses on the Likert scale were dichotomized as agree (agree or strongly agree) and disagree (disagree or strongly disagree) to simplify the analysis. Several participants wrote in a neutral response (e.g. 2.5 between the provided options of 2 = disagree and 3 = agree); such responses were attributed to a more negative attitude towards VVT. For instance, in response to "Vibrator treatment was convenient", a response of 2.5 was categorized as disagree, whereas for a negative statement, "Vibrator treatment is painful", a response of 2.5 was categorized as agree. In this way, we attempted to limit bias favoring the treatment.

Results

Of 69 patients to whom VVT had been suggested, all agreed to receive questionnaires. Excluding one patient who did not receive a packet due to clerical error (two potential participants had the same first and last name), 68 questionnaires were sent. Thirteen women did not return the questionnaire. An additional three withdrew by returning questionnaires saying they did not want to participate. One returned a questionnaire incomplete for key information and two were excluded because they noted in their response that they did not purchase or use the vibrator or had used VVT for sexual dysfunction, not pain. The remaining 49 questionnaires (72% response) were included in the analysis. Demographics (i.e. age, education, race) of women who did not complete the study did not significantly differ from participants.

Participants had a median age of 30 (range 19–68 years); 86% of all respondents were white (Table 1). Seventy-six percent were married and 86% had finished at least college. Over a third (39%) reported no other medical problems. Patients reported a median duration of vulvar pain and dyspareunia of two years (range 0–23) and three years (range 0–30), respectively. A third of women described having previously owned a vibrator, but only two women described ever having previously used a vibrator for vulvar pain. Only two had used vaginal dilators for vulvodynia. Ten percent had tried physical therapy.

Over 80% of patients purchased the device on-line or by phone (82%) and these patients were significantly more likely to have received adult-content emails (94 and 79%)

Table 1. Patient characteristics.

Characteristic	Total *N*	*N* (%) or Median (range)
Median age in years (range)	49	30 (19–68)
Race *n* (%)	49	
White		42 (86)
Black		0 (0)
Asian		2 (4)
Other/unknown		5 (10)
Education *n* (%)	49	
Less than or some high school		0 (0)
Finished high school		4 (8)
Some college		3 (6)
Finished college		14 (29)
Postgraduate		28 (57)
Marital status *n* (%)	49	
Married		37 (76)
Single with partner		6 (12)
Single without partner		6 (12)
Previous treatment *n* (%)	49	
Lidocaine		15 (31)
Estrogen		18 (37)
Dilator		2 (4)
Vibrator		2 (4)
Physical therapy		5 (10)
Antibiotics/antifungal		22 (45)
Narcotics		3 (6)
Median years of vulvar pain (range)	46	2 (0–23)
Median years of painful intercourse (range)	43	3 (0–30)

compared to those (11%) who made a store purchase ($p < 0.05$). Later in the questionnaire, 79% noted that they would have preferred to receive the device from their doctor. The median duration of treatment was five months (range 1–18), three days per week (range 0.5–7) and one time per day (range 0.5–2). Most patients (80%) preferred the low or medium frequency setting and nearly all (>90%) performed treatment while reclining. No complications were reported.

Constructs of VVT acceptability were assessed with Likert-style questions (Table 2). Agreement between similar questions was uniformly high (Pearson's correlation coefficient >0.3). For example, statements "The time I needed for vibrator treatment was reasonable" and "Vibrator treatment was convenient" had a Pearson's correlation coefficient of 0.54 ($p = 0.0001$) indicating strong consistency among similar items. Over 90% reported that the treatment was affordable, was easy and required reasonable time for treatment. Seventy-three percent rated the treatment as convenient. Nearly all patients (94%) reported understanding the instructions and the rationale for the treatment.

Table 2. Acceptability measures for vulvar vibration therapy.

Statement	*N*	% Agree	% Disagree
The vibrator is easy to use	48	94	6
The vibrator was affordable	49	98	2
Obtaining the device was easy	48	85	15
I was able to maintain privacy in obtaining the device	48	83	17
I was able to find time for the vibrator treatment	48	71	29
The time I needed for vibrator treatment was reasonable	48	94	6
I understood the instructions for the vibrator treatment	47	94	6
I was satisfied with the way I purchased my vibrator	49	69	31
I would have preferred to receive the vibrator from my doctor	48	79	21
Vibrator treatment was convenient	49	73	37
The sound of the vibrator is too loud	49	35	65
My partner assists with treatment	45	44	66
I felt supported in the use of this treatment	49	90	10
I felt comfortable referring to the device as a "vibrator"	49	82	18
The vibrator is comfortable to use	49	76	24
Vibrator treatment is painful	48	42	58
This treatment was embarrassing	49	45	55
The appearance of the device was professional	48	69	31
I was comfortable with my doctor offering the vibrator treatment	49	90	10
Vibrator treatment is frightening	49	12	88
I felt comfortable using the vibrator in my home	49	90	10
I use the vibrator when no one else is home	49	45	55
I always follow my doctor's instructions	49	88	12
I am frustrated with previous treatments	49	86	14
Prior to using the vibrator, I felt confident it would help my pain	48	56	44
I understood the rationale given for this treatment	49	98	2
I understood the reason my doctor prescribed a vibrator	48	94	6
Vibrator treatment makes sex more enjoyable	42	74	26
Sex is less painful since I started vibrator treatment	41	73	27
Overall, vibrator treatment is an acceptable treatment for my pain	48	83	17
The device is an acceptable long-term treatment for pain	48	75	25
I plan to continue vibrator therapy for my pain	49	84	16
I would recommend this treatment to women with similar pain	48	88	12
Overall, I am satisfied with vibrator treatment	48	83	17

Seventy-six percent of patients reported that treatment was comfortable; yet, approximately half of patients responded that VVT was painful. Nearly half of patients felt that the treatment was embarrassing and a third acknowledged a statement that the appearance of the device was unprofessional. The majority of patients (90%), however, responded both that they felt comfortable using the treatment in their homes and that they felt supported by their partners in using this treatment. In terms of perceived symptom response, 83% responded that VVT was an acceptable treatment for their pain; over 70% of responders reported both that sex was less painful and was more enjoyable after treatment with VVT. Over 80% of patients reported overall satisfaction with VVT, plans to continue treatment long-term and a willingness to refer other patients with similar complaints for VVT.

Discussion

Vulvar vibration therapy, or VVT, is a novel treatment approach to residual or refractory vulvar discomfort that we have offered empirically to patients after incomplete response to other conservative treatments. Based on theories of myalgias and muscle tension (Laessoe, Nielsen, Biering-Sorensen, & Sonksen, 2004) contributing to vulvodynia, combined with the known anti-nocioceptive properties of vibration (Hollins, Roy, & Crane, 2003), we theorized that this approach would offer a safe, inexpensive, private and convenient alternative (or supplement) to physical therapy, with the possibility of real pain response. Anecdotally, we have seen an encouraging response to this approach, but have not yet performed the definitive trial to evaluate the effectiveness of VVT compared to other modalities. The above survey is a preliminary study to introduce the idea of VVT and to assess its acceptability for patients before launching a clinical trial.

According to questionnaire responses, the majority of patients found VVT to be acceptable and were satisfied with vibrator treatment (83%). Though the majority rated treatment as comfortable, nearly half described it as painful. Written comments indicated that this discrepancy might reflect a change over time as many patients reported improved comfort as treatments progressed and vulvodynia improved. Most said they would recommend VVT to other women with similar symptoms. Intriguing is that a majority of women reported a decrease in their pain with intercourse (73%) and an increase in their enjoyment of sex (74%). While the majority of women reported being comfortable using the vibrator at home (90%), most would have preferred to receive the vibrator from their physicians (79%) rather than purchasing it independently. Despite the fact that 45% said that the treatment was ''embarrassing'', 84% indicated that they plan to continue using this therapy.

This study has several important limitations. First, as a descriptive study, with no control group this study is not designed to evaluate the therapeutic response to VVT. Second, results from this questionnaire are vulnerable to biases, particularly related to a study population of women willing to respond to the survey. Assuming the worst case scenario (the 17 women who did not return or complete the questionnaire or declined participation all having a negative perception of VVT), about half of women would have acknowledged convenience (55%), comfort (56%), improved enjoyment of sex (53%), less painful sex (54%) and VVT as an acceptable treatment for pain (51%). Third, though internal validity was suggested by good correlation between similar questions, the questionnaire is original and therefore not validated. Fourth, the generalizability of our study is limited due to our study population being small, primarily white, married, well-educated and from a single geographic area.

The value of this study is in the introduction of a novel therapy, based on sound physiological theory (Sonksen et al., 2007) with the advantages of reasonable cost, practicality, privacy and the possibility of symptomatic improvement. Our results indicate that most women surveyed consider VVT to be an acceptable approach to their refractory or residual vulvodynia. Thus, we believe that VVT, as a treatment for residual or refractory vulvodynia, warrants an objective evaluation of its effectiveness on pain, quality of life and sexual function through a randomized controlled trial.

Notes on contributors

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Dr. Lamvu received her medical degree from the Duke University School of Medicine. She completed her OB/GYN residency and fellowship in Advanced Laparoscopy and Pelvic Pain at the University of North Carolina at Chapel Hill. Dr. Lamvu has published articles in several medical journals and presented her research at many conferences throughout the country. She is an active member of the American Association of Gynecologic Laparoscopists, International Pelvic Pain Society, and American Society for Reproductive Medicine. Prior to joining the Loch Haven OB/GYN Group at the Florida Hospital in Orlando in 2007, Dr. Lamvu served as assistant professor for the Division of Advanced Laparoscopy and Pelvic Pain at UNC.

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