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Recent Research on the Treatment of Vulvodynia

By Christin Veasley, B.Sc., and Phyllis Mate, M.A.

Christin Veasley is the director of professional programs and research at NVA and has written several articles for our newsletter. Phyllis Mate has a master's degree in clinical psychology and has served as the executive director of NVA since 1996.

In October 2004, NVA participated in an important research conference, entitled *Vulvodynia and Sexual Pain Disorders,* organized and co-chaired by NIH vulvodynia grant recipient, Gloria Bachmann, MD, associate dean of women's health, and Ray Rosen, MD, professor of psychiatry and medicine, both of the University of Medicine and Dentistry of New Jersey. The basic science research presentations at the conference were previously summarized in the *NVA News* (Winter 2004) and this article reviews the clinical studies presented. It should be noted that the results from many of the treatment efficacy studies are based on small sample sizes.

Clinical Assessment

In any clinical research, standardized measures are essential to assess treatment outcome. Currently, the Q-tip test, in which different areas of the vestibule are palpated with a cotton swab, is the most widely used technique to evaluate vulvar vestibulitis syndrome (VVS). Even though this test is considered *clinically* useful to locate areas of the vulva that are hypersensitive, it is not a standardized method of pain assessment that can provide quantitative measures of pain and sensitivity thresholds. Caroline Pukall, PhD, of Queen's University in Ontario, Canada, described two recently developed methods to assess pain and sensitivity thresholds in women with VVS. She presented data from two studies that she and her colleagues performed in their attempt to develop standardized methods of vulvar pain assessment. In the first study, 13 women with VVS and an equal number of

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Practice Patterns of Clinicians Treating Vulvar Pain

By Glenn Updike, M.D.

Dr. Updike is an assistant professor in the University of Pittsburgh Department of Obstetrics, Gynecology, and Reproductive Sciences at Magee-Womens Hospital. Dr. Updike's clinical interests include vulvar disease, cervical dysplasia, and health care for women with physical disabilities.

The effective treatment of vulvodynia, a common condition, is a challenge for providers of women's healthcare. A recent investigation by Bernard Harlow, PhD, and Elizabeth Stewart, MD, of Harvard Medical School, demonstrated that up to 16 percent of women suffer from chronic lower genital tract pain at some point in their lives.[1] The International Society for the Study of Vulvovaginal Disease describes two distinct subsets of vulvodynia: generalized and localized vulvodynia.[2] Although there have been recent changes in the nomenclature of vulvodynia, clinicians have long recognized that some women suffer from pain or burning that is diffusely distributed throughout the vulva, while other

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matched pain-free controls were tested for touch and pain thresholds using modified von Frey filaments (small nylon fibers similar to the bristles of a toothbrush that are about 5 centimeters in length and made of variable thickness). In a second study, 14 women with VVS and an equal number of matched controls underwent pain threshold testing with a vulvalgesiometer, a hand-held device with a cotton swab tip that permits the exertion of a wide range of standardized pressures. She found that use of the filaments and vulvalgesiometer resulted in significantly lower pain thresholds in women with VVS compared to controls. In addition, testing with the filaments resulted in significantly lower tactile (touch) thresholds in women with VVS. Eliciting pain with the filaments did not yield a description of "burning," but rather a "pinching" or "prickling" type pain, likely due to their small contact area. Pain testing with the vulvalgesiometer replicated the "burning" pain sensations that women with VVS report experiencing during intercourse; however, because of the relatively large surface area of its cotton-swab, the vulvalgesiometer was not able to capture any difference in tactile sensitivity between groups. Pukall concluded that each method tests a different aspect of sensation. In summary, the modified von Frey filaments accurately measure tactile thresholds whereas the vulvalgesiometer is a reliable tool for measuring pain thresholds in vulvodynia patients. These two methods of assessing sensory abnormalities in women with vulvodynia can serve as standardized measures of treatment outcome in both clinical and research settings.

Rosemary Basson, MD, of Vancouver Hospital in Canada, described the clinical assessment of women with VVS, highlighting various issues to be addressed at the time of diagnosis and follow-up. She emphasized the importance of including both partners in collecting information on the couple's background and sexual difficulties (assuming the woman is in a relationship), as well as details of the evolution and consequences of the patient's pain. During individual interviews, each partner's sexual response, past sexual experiences, medical history and significant personality traits are noted and his/her goal in seeking help is also discussed. Allodynia is assessed using a Q-tip or vulvalgesiometer and a pelvic exam is performed to aid in diagnosis, identify concurrent conditions (if any), and assess muscle tone. The pelvic exam also enables the patient and her partner to understand the location(s) and severity of pain. In the follow-up assessment, Basson measures the severity of provoked/unprovoked pain and sexual satisfaction, and includes details of intercourse (if attempted), patient's current understanding of pain, stressors, other medical conditions and tolerance of prescribed medications.

Common Treatment Practices

Hope Haefner, MD, co-investigator on an NIH-funded vulvodynia study with Barbara Reed, MD, both of the University of Michigan Medical School, presented a treatment algorithm recently develop-

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ed by a group of 14 vulvovaginal experts. Haefner and her colleagues reviewed existing medical literature on vulvar pain, with specific emphasis on patient management, and wrote *The Vulvodynia Guideline*, published in the *Journal of Lower Genital Tract Disease* (January 2005). The article reviews all treatment modalities that have been described for managing chronic vulvar pain and provides a summary of the published evidence on each modality's efficacy. Haefner noted that while numerous interventions have been described in the medical literature, very few controlled trials have been performed to verify treatment efficacy. This has left clinicians with little information as to which treatments should be selected as first-, second- and third-line strategies for managing symptoms of vulvodynia. *(A report on the guidelines will appear in the next edition of* NVA News.*)*

Glenn Updike, MD, of the University of Pittsburgh, Magee-Womens Hospital, presented a poster describing the current practice patterns of clinicians treating vulvar pain syndromes (see related article, page 1). Updike sent a cross-sectional survey to 327 healthcare providers on the NVA's clinician referral list. The survey asked which treatments they use to manage the symptoms of generalized vulvodynia and VVS. Slightly more than 50 percent returned completed surveys. Overall, the most common treatment used by respondents was tricyclic antidepressants. Physical therapy, estrogens, injected or topical steroids, and interferon were equally likely to be recommended in the treatment of generalized vulvodynia and VVS. For the treatment of generalized vulvodynia, respondents were more likely to use tricyclic antidepressants, gabapentin (Neurontin®), and counseling, and less likely to use local anesthesia and vestibulectomy. Updike concluded that clinicians use a wide variety of treatments to manage the symptoms of vulvodynia and employ different approaches for each subtype. He also emphasized that large clinical trials will be necessary to establish the efficacy of different types of treatment.

Topical Treatments

Frank Dreher, PhD, of Neocutis SA, a Swiss company that provides innovative topical preparations for dermatological and gynecological conditions, presented a poster on behalf of colleagues from Neocutis and the University Hospital Lausanne, on a new topical preparation for the treatment of VVS. Previous research studies have provided evidence that an altered immune response may play a role in the pathology of VVS. Therefore, the group hypothesized that a topical application of anti-inflammatory cytokines (substances involved in anti-inflammatory reactions) may help to restore a normal immune balance in women with VVS. Researchers presented data on 11 women between the ages of 20 and 39, with a confirmed long-term history of VVS. Patients were asked to apply a topical preparation of cytokines and other proteins twice daily on the lower part of the vestibule. If symptoms lessened or disappeared, patients were advised to continue application once daily. Clinical assessment was performed before treatment, at eight weeks and thereafter on an every-other-month basis. All 11 patients who followed the protocol for at least three months experienced a significant reduction in pain level after four to eight weeks. Most patients reported a major improvement in the quality of their sexual lives and did not report any adverse side effects. There were no changes in the vulvovaginal flora and no vaginal infections were observed. The researchers are performing further studies to analyze the protein composition of the cream, specifically cytokine and growth factor profiles, and are organizing a randomized, double-blind, placebo-controlled trial to test the treatment's efficacy in a larger group of women.

Susan Kellogg-Spadt, PhD, of the Pelvic & Sexual Health Institute at Graduate Hospital in Philadelphia, presented a poster on the effectiveness of a topical capsaicin cream in the treatment of VVS. Capsaicin is a derivative of red pepper that may reduce VVS pain by depleting Substance P (a protein substance that increases transmission of pain impulses). In the retrospective study, Kellogg-Spadt reviewed the charts of 52 patients with VVS (18 percent of whom also had interstitial cystitis), who had been treated with topical capsaicin cream, applied 20 minutes daily over a period of 12 weeks. Six weeks after treatment ended, patients'

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pain and dyspareunia scores were significantly lower than their pre-treatment scores. Furthermore, the follow-up data showed that women reported more success after the initial 12-week treatment period if they subsequently used the capsaicin on a once-a-week maintenance basis, rather than terminating treatment completely. Kellogg-Spadt concluded that this topical treatment can play a significant role in reducing the discomfort of VVS, allowing for more frequent sexual activity. Plans are underway to conduct a multi-center placebo-controlled trial on capsaicin treatment for VVS.

Nerve Blockades and Injections

Andrea Rapkin, MD, and John McDonald, MD, of the UCLA Medical Center, presented a poster summarizing preliminary data from an ongoing pilot study to determine the efficacy of a neural multi-level treatment approach for VVS. Rapkin and McDonald hypothesized that interrupting the pain signals from the periphery with repeated injections of local anesthetics would alter central (spinal cord and brain stem) facilitation of pain. Ten women were enrolled and followed a treatment protocol consisting of three anesthetic injections per visit, during five visits spaced two to three weeks apart. Initially, all areas of the vestibule exhibiting tenderness were injected with a local anesthetic. Next, bilateral anesthetic pudendal blocks were performed. Lastly, an anesthetic block was performed at the S2-S4 spinal cord segment to target groups of nerve cell bodies known as ganglia. Patients were asked to rate their pain on a daily basis, and several surveys and physical tests were performed before and after the treatment course to assess pain level, sexual function, depression, anxiety, behavior and attitude. Nine out of 10 patients reported lower pain levels after treatment; however, baseline scores on anxiety, depression and sexual functioning did not significantly change post-treatment nor did they predict the patient's response to treatment. Rapkin and McDonald are encouraged by the preliminary results and plan to conduct a larger, placebo-controlled trial in women with VVS.

Candace Brown, MSN, PharmD, of the University of Tennessee Health Science Center, with colleagues from Cornell University and Robert Wood Johnson Medical School, collected pilot data on the efficacy of an intramuscular botulinum toxin, i.e., Botox, type A (BTX/A) injection into the levator ani muscle of the pelvic floor in VVS patients. The goals were to relieve pain experienced with intercourse, reduce pelvic floor tension and instability, and alleviate vestibular hypersensitivity in women with VVS. At their first visit, two patients who previously had been unresponsive to medical treatment were given two injections of BTX/A (20 units) into the 5 and 7 o'clock regions of the vestibule; at their second visit 12 weeks later, they were given injections with double the amount (40 units) of BTX/A. The patients were instructed to keep weekly diaries describing pain severity and underwent surface electromyography (sEMG or "biofeedback") before and after treatment to evaluate any change in pelvic floor activity. They were also tested with a vulvar algesiometer to assess any change in hypersensitivity of the vestibule. The investigators found that treatment with BTX/A modestly reduced intercourse-related pain, and reduced pelvic floor hypertonicity and variability at 12 and 24 weeks, but only relieved vestibular hypersensitivity at 24 weeks. Relief from intercourse-related pain was most pronounced two weeks post-injection, with pain gradually worsening over the 12-week period. The degree of relief, including changes observed in pelvic floor activity, appeared related to the dosage. The authors proposed that BTX/A injections may be effective in alleviating the symptoms of VVS and intend to further investigate the dose relationship and the overall efficacy of the therapy.

Marjorie Green, MD, of Harvard Medical School and Marian Arbesman, PhD, investigated the efficacy of trigger point injections in women who experience introital dyspareunia, pain with intercourse at the entrance to the vagina. They hypothesized that myofascial dysfunction (pain and tenderness in the muscles and adjacent fibrous tissue) plays a role in the etiology or maintenance of introital pain located at the 5 and 7 o'clock sites of the vestibule. Ten women with dyspareunia at these sites, who did not display evidence of VVS,

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Pitfalls in the Application of Clinical Classification of VVS

By William Ledger, M.D., FACOG

Dr. Ledger is the Given Foundation Professor of Weill Medical College of Cornell University and Chairman Emeritus of the Department of Obstetrics and Gynecology at New York Presbyterian Hospital. His primary research focus is infectious vulvovaginal disease and vulvar vestibulitis.

The current fad in medical care is an over-emphasis upon evidence-based medicine to determine therapeutic strategies for patients. In this approach, patients are diagnosed based on the findings of a physical examination and classified accordingly. Relying exclusively on clinical classification, data are gathered from a host of prospective studies, hopefully double-blinded, to determine the best course of treatment for different medical ills. The logic of such an approach is difficult to refute, assuming that the classification scheme is valid. If not, this approach will not yield the best answers for women suffering with what I still prefer to call vulvar vestibulitis.

Incorrect assumptions

The scientific basis for most medical schemes of care is biological and emphasizes classification in an attempt to establish order from the chaos of the complex pathophysiology of most diseases. This has led to the current terminology of *primary* and *secondary* vulvar pain: primary, the pain present with the first attempt to have intercourse; secondary, when previously comfortable intercourse becomes and remains painful. With this classification, these two separate clinical entities can each be subjected to prospective study in an attempt to find clues to its etiology or effective treatment strategies. The problem with this approach for both the physician and the patient is that this or any alternative clinical classification may not be asking the proper questions. Consequently, the answers achieved may not be the best for patient care. I'd like to cite an example of a rational and workable clinical classification that was subsequently discarded as more scientific information was obtained. In the 1950s and 1960s, based upon the observed reality that antibiotics were an ineffective treatment for patients with a pelvic abscess, a classification of abscesses was established that dictated the proper operative approach to the care of these patients. A ruptured pelvic abscess was a medical emergency that required immediate laparotomy (a surgical incision into the abdominal cavity) to remove all infected tissue. An intact pelvic abscess that ballooned into the vagina could be accessed vaginally and drained, achieving a cure without subjecting the patient to laparotomy. An intact pelvic abscess that was not accessible vaginally required the surgery to remove the intact abscess before it had a chance to rupture.[1] It was a useful and practical clinical classification that worked. However, it became obsolete when the role of anaerobic bacteria in abscess formation was discovered in the 1970s and antibiotics that were effective against these anaerobes were introduced into clinical practice.[2] Based on new information gained from scientific study, non-invasive treatment of pelvic abscess became the new standard of care and the previously useful classification scheme was discarded.

Prospective studies of mode of therapy

Another current standard of investigation is the prospective study of therapeutic interventions to determine the best care. There are myriad examples of this. Bacterial vaginosis (BV) in the pregnant woman has been associated with premature labor and delivery. Observing this, the next step was to determine whether using therapeutic intervention with antibiotics in pregnant women with bacterial vaginosis would decrease the incidence of premature delivery. The largest study to date showed no benefit to this intervention, but, for me, the unanswered question is, *what is bacterial vaginosis*? Is it determined by bedside use of the Amsel criteria [3] or the Nugent criteria in which the diagnosis is made by the microscopic evaluation in a central laboratory of the Gram stain of a vaginal smear.[4] Although there is overlap between these two diagnostic criteria, many more patients are diagnosed with BV using the Nugent test than by the Amsel evaluations. Which population should you study when comparing therapeutic interventions? In addition, patients with BV have a variety of clinical presentations. They can be symptomatic, asymptomatic, spontaneously clear the condition and return to normal, or have recurrence of the condition after antibiotic treatment. This diverse population clearly doesn't lend itself to prospective therapeutic trials.

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Classification

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Relationship to Vulvar Vestibulitis

Anyone who has dealt with patients with vulvar vestibulitis has to be impressed with the variety of clinical manifestations. These women can present with continuous symptomatology or remain asymptomatic until they attempt to use a tampon or have intercourse. Upon examination, the vulvar vestibule can be inflamed with vestibular glands that are tender to the touch, or there may be no vulvar inflammation, even though there is extreme tenderness when the vestibular glands are touched. Vulvar vestibulitis is a diffuse clinical entity with a wide variety of precipitating events that parallel the unwelcome odyssey of vulvar pain in most patients. Patients report that symptoms began with what was believed to be a severe vaginal yeast infection, a new sexual partner, a new type of contraception, laser treatment of the vulva or an abdominal operation. After the onset of symptoms, the difference for these women is that the inflammation and pain persist. Those investigators who favor a neuropathic explanation of this syndrome classify it as dyesthesia, allodynia, and hyperalgesia. My concern is that attempts to use *any* type of clinical classification may segregate this diffuse population improperly. Consequently, the groups chosen for subsequent intervention studies may not share a common underlying causation, making the validity of the results questionable.

An alternative focus for future study

Rather than rely on patients' clinical presentations, it makes more sense to me to delineate measurable differences among women with vulvar vestibulitis. Each subgroup can then be assessed to determine if there is a superior treatment protocol for patients with that subtype. In the past decade, I have been impressed with the work done by Steven Witkin, PhD, and his laboratory team here at Cornell, demonstrating biologic differences in subgroups of women with vulvar vestibulitis. A genotype associated with prolonged and increased severity of inflammation, homozygosity at allele 2 of the polymorphic interleukin-1 receptor antagonist gene (IL1-ra), is more prevalent in women with vulvar vestibulitis than in controls.[5] Women with vulvar vestibulitis have elevated vestibular tissue levels of the pro-inflammatory cytokines, interleukin 1-ß and tumor necrosis factor α.[6] There is also evidence of defective regulation of the pro-inflammatory immune response in these women, with an inability to down regulate pro-inflammatory interleukin 1-ß activity by IL1-ra.[7] When these women are identified by laboratory tests, prospective treatment trials can determine whether treatments that aim to increase tissue IL1-ra levels or other inflammatory blockers might be beneficial. Treatment of patients with interferon a, known to induce the local tissue induction of IL1-ra, is a future treatment study possibility. Most recently, the Cornell research group found that another genetic variation, the MBL allele MBL*B, is more common in women with vulvar vestibulitis.[8] That biologic difference could also be a factor in forming another subgroup of patients to be studied.

In conclusion, any prospective clinical trial should be preceded by laboratory studies to determine if the potential patients for the study share certain observed abnormalities. Then treatment regimens can be compared. The classification of patients based on observed laboratory findings, rather than clinical variability, would be a different approach than the one currently in vogue. I think it worth a try.

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Call to Action: Write Your Legislators May 23rd to 27th

NVA Coordinates First Vulvodynia Research Advocacy Week

Women from all over the country will visit and send e-mails or letters to their U.S. Senators and Representatives, as part of the first National Vulvodynia Research Advocacy Week, May 23-27th, 2005, a campaign intended to raise awareness and solicit Congress' support for increased vulvodynia research funding. NVA has developed a lobbying packet for support leaders who have volunteered to coordinate visits to their representatives' local offices. This advocacy effort is a prelude to an upcoming Capitol Hill briefing on vulvodynia and two other gynecological pain disorders, endometriosis and uterine fibroids. The briefing was organized by The Society for Women's Health Research, the country's largest non-profit women's health advocacy group, and will take place on June 9th, 2005, in Washington, DC. During the week of May 23rd, we are asking you to contact your legislators and urge them to send their Capitol Hill staffers to the briefing.

If Congress is to remedy the lack of federal funding for vulvodynia research, legislators need to see that their constituents care about the issue. We elect these leaders to represent our interests, so please make your voice heard! Write to your legislators during the week of May 23rd and ask your family members and friends to do the same. Your participation will require minimal time and effort. Go to the home page of *www.nva.org* and click on the link to Write Your Legislator, where you will find a letter template and simple instructions. With a simple mouse click, your individualized letter will be sent to all your Congressional representatives and to any family members and friends that you designate. (Then they will receive the same template to send to their representatives.)

We'd like to express our appreciation to volunteer Lindsey Rossler for organizing this advocacy event. *Together we can make a difference!*

Research

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were included in the study. Participants were not included if they had any discharge, burning, pathology, evidence of vestibular tenderness with Q-tip application or indurated (hardened) vestibular glands. Patients were first injected with a local anesthetic. By inserting a finger in the vagina, trigger points were identified and then the anesthetic was administered through the skin into the trigger point. The patients were encouraged to have intercourse within two hours of the intervention and rate their pain on a scale of 1 to10. If they experienced relief, they were brought in and re-examined within the week. If patients still had pain, they received injections containing a mixture of the anesthetic Marcaine and the steroid Depo-Medrol. Again, they were encouraged to have intercourse and return in two weeks to be re-examined. Green and Arbesman reported that after the first injection, patients' pain ratings dropped dramatically from an average of 9.2 to 0.9. One patient's pain was completely resolved and she was not included in the second portion of the study. Nine women underwent the second injection and the average pain score declined from 9.2 prior to injection to 3.6 two weeks post-injection. Two months later, 50 percent of the women were still pain-free. Green and Arbesman proposed that clinicians consider using trigger point injections, with local anesthetic alone or combined with steroids, in treating patients without underlying pathology who experience pain with penetration only at the 5 and 7 o'clock locations of the vestibule.

Surgical Procedures

Andrew Goldstein, MD, of the Center for Vulvovaginal Disorders in Washington, DC, presented data from a retrospective study that assessed long-term patient satisfaction with vulvar vestibulectomy for the treatment of VVS. Twelve to 60 months after the procedure, 69 VVS patients who had previously undergone a complete vulvar vestibulectomy with vaginal advancement were con-

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tacted. Sixty-eight women agreed to participate in the study and the average time post-surgery was 26 months. Prior to surgery, 72 percent were unable to have sexual intercourse because of the severe pain they experienced during intercourse; following surgery, only 9 percent were unable to have intercourse. Prior to surgery, 86 percent had sexual intercourse less than twice per month, whereas, after surgery, 76 percent had intercourse at least twice per month (and 51 percent reported once per week). Ninety-three (93) percent reported that the change in appearance of the vulva following surgery was not significant and 82 percent reported no change in their ability to have an orgasm. Ninety-three (93) percent said that they would undergo the surgery again and would recommend the treatment to other women with similar symptoms. Ninety-four (94) percent reported that their symptoms were not made worse by the surgery whereas 6 percent reported worsening of symptoms. Some of the explanations physicians gave for exacerbation of pain were scar tissue formation that would eventually resolve, inadequate healing of tissue, blood blister formation and the presence of generalized vulvodynia. Given most patients' positive attitude and long-term satisfaction, Goldstein proposed that vestibulectomy not necessarily be considered only as a "last resort." He suggested that cautionary statements made to patients prior to surgery include a reasonable estimate of possible complications.

Alfredo Nieves, MD, of the University of Tennessee College of Medicine, presented a study that sought to determine the effectiveness of a laparoscopic surgical technique to relieve painful symptoms associated with pudendal nerve entrapment (PNE). The study participants were 12 women who had received a diagnosis of pudendal nerve entrapment (PNE) after undergoing a diagnostic pudendal nerve block. Patients were selected for surgery only if their pain was not reduced by at least 50 percent after six or more weeks of oral medication and physical therapy. During the outpatient laparoscopic procedure, any entrapment was released and any concomitant pathology, such as hernia, endometriosis and pelvic congestion, was also treated. (Seven of the 12 patients were diagnosed with one of these other conditions.) The average follow-up period was three months and 10 of the 12 patients reported greater than a 50 percent reduction in pain, as measured by visual analogue scale ratings and the McGill pain inventory. In addition, they reported a 50 percent improvement in quality of life. None of the participants needed further surgery and no major complications occurred. Nieves noted that even though the follow-up period reported in the pilot study was short-term, the results appear promising and further evaluation is warranted.

Physical Therapy

Elke Reissing, PhD, of the University of Ottawa in Ontario, Canada, presented a study that sought to determine whether pelvic floor muscle tension or hypertonicity is associated with VVS. Twenty-nine women with VVS and an equal number of matched controls underwent two separate pelvic floor examinations by different physical therapists unaware of the diagnostic status of the participants. The therapists assessed muscle tonicity and strength as well as tissue elasticity, and found that compared to the control group, women with VVS demonstrated significantly more vaginal hypertonicity (increased muscle tension), lack of pelvic muscle strength and restriction of the vaginal entrance. Reissing concluded that these findings indicate that pelvic floor pathology plays an important role in perpetuating and potentiating the intercourse-related pain associated with VVS.

Talli Rosenbaum, PT, of the Tel Aviv Sex Therapy Clinic in Tel Aviv, Israel, presented data on the efficacy of physical therapy in women with VVS, dyspareunia and vaginismus. Specifically, Rosenbaum's treatment protocol included education, behavioral techniques and exercises designed to facilitate relaxation, positive body image, normal pelvic floor and related muscle tone and pain relief. Other modalities included pelvic floor surface electromyography (sEMG or "biofeedback"), ultrasound, transcutaneous electrical nerve stimulation (TENS) as well as traditional "hands on" techniques, e.g., massage, stretching and vaginal dilation.

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With a treatment course that ranged from four to 16 visits, 53 percent of VVS patients reported complete resolution of symptoms and 85 percent reported significant improvement. Both Reissing and Rosenbaum emphasized the importance of including a physical therapist trained in pelvic floor rehabilitation in the treatment strategy for VVS patients.

Psychotherapy and Self-Management

Robin Masheb, PhD, of Yale University Medical School, presented data from her NIH-funded research study evaluating the efficacy of two psychosocial treatments on vulvodynia patients: cognitive behavioral therapy (CBT) and supportive psychotherapy (SPT). The CBT treatment incorporated pain coping skills, whereas the SPT treatment consisted of therapeutic listening. In her study, 50 women with either VVS or generalized vulvodynia who had symptoms for an average of 8.5 years, were randomly assigned to CBT or SPT and received 10 weeks of manual-based treatment by doctoral level psychologists. She found that both patient groups demonstrated significant improvement in pain severity and sexual functioning immediately following treatment, but that the CBT group also demonstrated significant improvement in point tenderness. Both physicians and patients' self-report measures indicated a 50 percent average reduction in pain. Improvement in pain severity and sexual functioning were maintained at six-month follow-up, and evidence of improvement in affective (emotional) distress was also present at six months. Furthermore, women who received CBT felt more satisfied with the treatment they received, reported greater global improvement and felt it was a more credible treatment than women who received SPT.

Conference co-organizer Raymond Rosen, MD, of the University of Medicine and Dentistry of New Jersey, and Susan Kellogg-Spadt, PhD, of Graduate Hospital in Philadelphia, presented preliminary data from a study designed to compare the efficacy of two common treatments, amitriptyline (Elavil®) and a topical corticosteroid, to a multifaceted self-management approach. The self-management training was conducted over 10 to 12 sessions in a group setting with two co-therapists, a sex therapist and nurse practitioner. Each group was provided with instruction and training on three components: cognitive therapy, physiotherapy/self-massage in which women were taught how to massage the pelvic floor musculature surrounding the vagina, and sex/couples therapy. The investigators measured treatment outcome by administering multiple surveys assessing pain, quality of life, sexual distress, anxiety and depression. Rosen and Kellogg-Spadt presented preliminary data on 17 women with VVS and generalized vulvodynia who had completed the self-management portion of the trial. The average age of participants was 46 years and 57 percent were pre-menopausal. The mean duration of symptoms was 9.9 years and approximately 50 percent of the patients experienced symptoms of depression. After the training, the participants reported a reduction in pain during activities unrelated to intercourse, but pain *with* intercourse was unchanged. Rosen and Kellogg-Spadt noted some limitations in the study, such as a small sample size, current lack of follow-up data and having enrolled women with different subsets of vulvodynia in the treatment group. However, given the protocol's high degree of acceptability by patients, as well as the improvement reported on measures of pain and sexual distress, they concluded that self-management intervention warrants further evaluation.

Future Research

Although close to 30 different therapies for managing vulvodynia have been described in the medical literature, little data exists on their effectiveness. The above studies on current treatments and promising new approaches provide hope to the millions of women who continue to search for effective ways to manage their pain. NVA remains committed to increasing research funding to study vulvodynia treatments. If you are interested in learning about the studies funded by NVA and the National Institutes of Health and/or donating to NVA's medical research fund, please visit our website: http://www.nva.org/for_medical_professionals/research_fund.html. ■

Patterns

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women have pain that is localized to one specific area. Decisions regarding the management of both subsets of vulvodynia have been difficult for a variety of reasons. Until recently, there had been no published guidelines for clinicians to follow in the management of patients with vulvodynia. Also, randomized clinical trials demonstrating the superiority of one therapy over another are rare. As such, clinicians typically have relied on personal experience to manage their patients with vulvodynia.

Recently, Harold Wiesenfeld MD,CM, and I conducted a survey to determine how "experts" in the field of vulvodynia are managing their patients. The results of this study, conducted by the University of Pittsburgh Department of Obstetrics, Gynecology, and Reproductive Sciences, will be published in an upcoming issue of the *American Journal of Obstetrics and Gynecology*.[3] Our investigation had multiple goals. First, we sought to determine which treatments for vulvodynia were used most frequently. Secondly, we were interested in finding out in what order these treatments were used; that is, what were the first, second and third lines of therapy in the clinician's management strategy. Finally, we hoped to discover how clinicians varied their treatment of vulvodynia depending on whether a patient presented with the generalized or localized variant of the condition.

In our survey, the most common therapy prescribed by clinicians was tricyclic antidepressants.

Our study surveyed 327 healthcare professionals who treat vulvodynia and were included on a referral list provided by The National Vulvodynia Association; 167 returned completed questionnaires. Approximately 70 percent of these clinicians were gynecologists, with anesthesiologists, dermatologists, family practice physicians, and physical therapists comprising the remainder of the group. The questionnaire consisted of 14 questions in each of three sections. The first section contained questions on procedures and tests performed in the evaluation of their patients with vulvodynia. The second section of the questionnaire described two clinical vignettes. The first vignette presented a patient with classical symptoms of generalized vulvodynia and the second presented a patient with the characteristic findings of localized vulvodynia. Respondents were asked to choose from a list of 12 common treatments which they would use as their first, second, and third lines of therapy for each of the clinical examples. The final section of the questionnaire asked clinicians about the lifestyle changes they recommend to their patients with vulvodynia.

The majority of clinicians surveyed perform tests to determine if there is an infective source of vulvar discomfort in their patients. Approximately 75 percent of respondents utilize office microscopy to assess for yeast and bacterial vaginosis, and two-thirds send a culture of vaginal secretions to a laboratory to determine if yeast is present. About 10 percent of respondents reported sending a Gram's stain to screen for bacterial vaginosis. Interestingly, about one-third of respondents perform either a vulvar biopsy or colposcopy in their evaluation of patients with chronic vulvar pain.

In our survey, the most common therapy prescribed by clinicians was tricyclic antidepressants such as amitriptyline. Although tricyclic antidepressants are the most commonly used therapy for both subsets of vulvodynia, they are more often used for generalized vulvodynia. In fact, 89 percent of respondents reported prescribing tricyclic antidepressants as part of their management strategy for generalized vulvodynia, with slightly more than 50 percent of respondents using them as the first line of therapy. The second most commonly prescribed therapy for generalized vulvodynia was gabapentin (e.g., Neurontin®), with 68 percent of respondents using it at some point in their management plans.

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Patterns

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For localized vulvodynia, 35 percent of respondents reported using topical local anesthetics such as Xylocaine as their first line of therapy, making them the most commonly prescribed first-line treatment. Tricyclic antidepressants were the second most commonly used treatment for localized vulvodynia, with 28 percent using them as their second-line therapy. As might be expected, surgery was performed much more often for localized vulvodynia than it was for generalized vulvodynia. For localized vulvodynia, 48 percent of respondents reported that they would use vestibulectomy (removal of the vulvar vestibule) as a management option. However, most clinicians would perform surgery as a last resort; only 3 percent of respondents said they would use vestibulectomy as their first line of therapy for localized vulvodynia.

A variety of non-pharmacologic therapies for the treatment of vulvodynia were reported in this survey. Clinicians often recommended physical therapy as part of the treatment plan for both generalized and localized vulvodynia (48 percent and 44 percent, respectively). Behavioral therapy was also frequently recommended for patients with vulvodynia, with about 25 percent of respondents recommending counseling to patients with generalized and localized vulvodynia. While vulvodynia is not a problem of psychological origin, the consequences that the condition has for the individual and her relationships may warrant the inclusion of behavioral therapy in the management plan.

There is little scientific evidence available to support or refute the many lifestyle changes that clinicians often recommend to patients with vulvodynia, however, it was interesting to note how experienced providers counsel their vulvodynia patients with regard to these issues. The most commonly recommended lifestyle adjustments were to wear loose-fitting clothing, wear only cotton underwear, and use unscented detergents, with about 75 percent of respondents making these recommendations. Two-thirds of the respondents reported advising patients to use unscented pads, avoid douching and discontinue use of feminine hygiene products. While most of these adjustments are made relatively easily, one lifestyle modification that requires considerably more effort is the adoption of a low oxalate diet. Despite evidence that the maintenance of a low oxalate diet offers no benefit to patients with vulvodynia,[4] 28 percent of respondents reported that they counsel their patients to follow the diet.

Until there is more rigorous scientific data available to guide management strategies in the treatment of vulvodynia, expert opinion is an important source of information for clinicians hoping to treat this condition efficiently and effectively. In addition, the results of this survey may help guide future research. Clinical trials should focus on the treatment modalities being used most frequently, to either prove or disprove their effectiveness. Until such time as the data is available, this survey provides insight on how experts in the field are providing care to women with this challenging condition.

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