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Biofeedback in Diagnosis and Treatment of Vulvodynia

By Howard I. Glazer, Ph.D.

Dr. Glazer is a clinical associate professor of psychology in the Department of Psychiatry, Weill College of Medicine, Cornell University/New York Presbyterian Hospital. His clinical practice encompasses a wide range of urogenital tract disorders, including urinary incontinence and vulvodynia.

Vulvodynia is a descriptive, not a diagnostic, term covering a wide range of disorders that have, as one component, pain in the vulvar area. In no other area of biofeedback practice is it more important to rule out all organic causes for the symptoms prior to commencing treatment and to treat patients only under referral from a specialty physician, not on self-referral. Sources of vulvovaginal discomfort include vaginal infections, hormonal changes, dermatoses, venereal disease, oncological disease, and trauma. Many women experience transient vulvar irritation from any of the above sources or from contact with irritants, including soaps, detergents, topical vulvar preparations used to treat some of the above conditions, prolonged or inadequately lubricated penile vaginal intercourse, and vulvar trauma associated with accidents or surgery. In most cases, the irritation does not need to be addressed once the underlying causes have been identified and treated. In vulvodynia, the regional pain persists after the original tissue irritation is resolved.

Definition and Treatment Overview

Vulvodynia is an essential pain disorder, diagnosed by exclusion of identifiable organic pathology. This extremely limited overview of the sources of vulvar pain symptoms is given to emphasize the necessity for a complete diagnostic workup, and appropriate medical treatment, before any biofeedback intervention is considered.

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Neurostimulation in the Treatment of Severe Vulvodynia

By Michael O. Seibel, D.O.

Dr. Seibel is the medical director of Pain Treatment Associates in Fort Worth, Texas. He is board certified by both the American Board of Pain Medicine and the American Board of Physical Medicine & Rehabilitation.

Neurostimulation is a procedure that has been used for many years to relieve pain in carefully selected patients with intractable severe pain. It involves the implantation of an electronic device that delivers low voltage electrical stimulation to the spinal cord or targeted peripheral nerve with the intent of "substituting" a tingling signal for a pain signal. Some current indications for spinal neurostimulators include Failed Back Surgery Syndrome, Complex Regional Pain Syndrome, arachnoiditis, peripheral causalgia, and Degenerative Disk Disease or herniated disk pain refractory to conservative and surgical interventions.

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One subset of vulvodynia, vulvar vestibulitis syndrome, is characterized by introital dyspareunia (painful sexual intercourse) and may involve swelling, erythema (redness), and exquisite tenderness to touch localized to the vestibule of the vagina. Patients with this condition typically suffer no discomfort unless there is direct pressure on the vestibule. These patients are often intercourse abstinent and, eventually, totally sexually abstinent for prolonged periods of time.

Because this condition has no known cause and is expressed as symptoms that interfere with sexual activity, it is not surprising that some have suggested that it is a psychological disorder. Research in this area has demonstrated clearly that this population shows no significant medical, psychological, or sexual history differences from normal matched controls (Meana, 1997). Conservative medical treatment for this condition includes low-dose tricyclics or anticonvulsants to block the nerve-mediated pain, medications to reduce inflammation such as antihistamines and cox-2 inhibitors, alpha-interferon injections, topical palliatives such as colloidal oatmeal, and topical anesthetics. If these interventions produce unsatisfactory results, the gold standard treatment for women with vestibulitis has been a vestibulectomy, the surgical excision of the affected area (Marinoff & Turner, 1992). Essential or dysesthetic (meaning unpleasant altered sensation) vulvodynia is a condition of diffuse, unprovoked vulvar burning, which can vary from mild to extreme and from intermittent to chronic. It tends to be progressive with respect to both chronicity and intensity of symptoms. It is of unknown etiology and may have no visible vulvar changes. Like vestibulitis, it tends to reduce sexual activity, leading frequently to sexual abstinence and the associated psychological and interpersonal consequences. Medical treatments for this condition include hormone replacement therapy (HRT), tricyclic antidepressants, antihistamines, anticonvulsants, muscle relaxants, topical palliatives and anesthetics. Surgery has not been shown to have any beneficial role in the treatment of this condition.

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P.O. Box 4491, Silver Spring, Md. 20914-4491
(301) 299-0775; FAX: (301) 299-3999
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Phyllis Mate

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Biofeedback Treatment of Vulvodynia

In brief, biofeedback is a self-regulation training technique derived from well established principles of human learning. Biofeedback is a technique, not a stand-alone treatment, that is one component of a behavioral training program to facilitate acquisition of pelvic floor muscle control. With the use of biofeedback, physiological change can be achieved by means of operant conditioning, a type of learning which occurs as a result of feedback, or the experience and awareness of the consequences of one's behavior. The first step in using biofeedback as a therapeutic tool is to understand the anatomy and physiology underlying the symptomatic dysfunction. This allows the selection and measurement, and ultimately voluntary control, of a physiological response.

In 1991, Alexander Young, MD, and his colleagues

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of the Cutaneous Vulvar Clinic at Columbia University College of Physicians and Surgeons approached me after noting that during intravaginal examination, the levator ani muscles (muscles in the anal area) of women suffering from vulvodynia showed considerable chronic "tension and spasticity." These specialists requested the use of biofeedback to correct this muscle abnormality.

I started working with the vulvodynia patient population using the standardized protocols and treatment regimes developed for the urological disorders of retention and incontinence. It was immediately noticeable that the patterns of electrical activity or surface electromyography (SEMG) of this population's pelvic muscles showed abnormally high tone (tension) and instability during rest, as well as weakness and instability during voluntary contractions. However, after a period of "trial and error" in working with these patients, I turned my focus away from these abnormalities. Although several patients had significantly strengthened their muscles (increased contractile amplitude) and relaxed their muscles (reduced resting amplitude) using biofeedback, they still showed little, if any, symptomatic benefit. Statistical analyses suggested that the variability of the SEMG signal, and not the strength or resting tension level of the pelvic floor muscle, was critical in pain reduction (Glazer, Rodke,1995). As would be expected, signal variability measures were clearly noted to vary directly in proportion to amplitude, both at rest and during contractions. In simple terms, the greater the muscle activity, the more the signal varied. Statistically correcting for activity level variability is accomplished by using the "coefficient of variation" as a measure of SEMG signal variability. This statistical measure of the muscle SEMG signal can then be used to compare differences between normal and symptomatic patients and to predict changes in pain level. The evaluation protocols have evolved to include the speed of contraction onset and release, as well as a statistical analysis to determine which type of muscle fibers are contributing to the overall muscle activity.

The goal is neither to strengthen nor relax the pelvic muscles, but to coordinate the pelvic floor musculature by stabilizing the SEMG signal. Accompanying this coordination is reduced speed of contraction onset and release times, and an increase in utilization of coordinated, faster-acting fiber subsets.

Evaluation of pelvic floor muscle function

The "Glazer" protocol for evaluating pelvic floor muscle function uses a five-segment evaluation sequence assessing pre-and post-baseline rest, as well as various muscle contractions. Patients are first taught how to lift or elevate the pelvic floor muscles and modify their relationship to body position and activity of the surrounding musculature. Automated protocol software instructs patients with both on-screen text and voice prompts to "flick," "work," or "rest" to let the patient know when to contract and when to relax the pelvic floor muscles. The five-segment evaluation sequence is as follows: (i) one minute at rest, pre-baseline; (ii) five rapid contractions (flicks) with a 10-second rest between each (phasic contraction); (iii) five 10-second contractions with a 10-second rest between each (tonic contraction); (iv) a single sustained contraction of 60 seconds (endurance contraction); (v) one-minute rest, post-baseline. This protocol is a similar sequence to that used in assessing pelvic floor muscles for incontinence. The difference is not in the sequence of muscle actions, but in the measurements taken.

During the pelvic pain protocol, in each contraction and relaxation period, measures include: pelvic floor muscle activity level; variability of activity level; statistically corrected variability level; speed of contraction onset and release; and analysis of the types of fibers that are active during tonic and endurance contractions. Another difference between the Glazer protocol and previous incontinence protocols is that accessory muscles, such as upper leg, thigh, buttock, and abdominal muscles, are not necessarily minimized. Each patient is assessed with the use of different combinations of accessory muscles. This is done in order to determine the best balance between keeping the patient's focus on the internal "lifting" sensation and, at the same time, maximizing the use of the muscle con-

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traction to result in a reduction in activity and variability in the subsequent rest period. We also focus on increased coordination as reflected in decreased contraction initiation and release times, decreased variability and increased participation of the faster coordinating fibers within the muscle. We look for an exercise position, contraction type, contraction duration, and number of repetitions that maximize the therapeutic value of the exercise. All patients are started on two 20-minute exercise sessions per day, each one consisting of 60 repetitions of 10-second contractions alternated with 10-second relaxation phases. All patients are required to use home training devices and intravaginal sensors in the conduct of their home exercises.

Patients return for office evaluations every two weeks for their second and third visits and then monthly for subsequent visits. The frequency of office visits is determined by the observation of the clinician of both SEMG and symptomatic changes and compliance of the patient in the conduct of home exercises. As mentioned earlier, pelvic floor muscle activity level changes are not enough, as many patients have shown improved muscle strength and relaxation with little therapeutic benefit. We believe that changes in the statistical measures of pelvic floor muscle electrical activity (i.e., amplitude, variability, speed of contraction onset/release and fiber type), reflect essential changes in how these muscles function and that they result in local pain reduction or elimination**.** The electrical activity of the pelvic floor muscle is an integral part of local physiological changes associated with pain involved in inflammation, reduced blood flow, neural hypersensitivity, etc. Modification of the electrical activity is believed to bring about changes in local physiology, reducing or eliminating the reflex mechanism that maintains the pain**.**

Research on Biofeedback for Vulvodynia

The first publication using SEMG-assisted rehabilitation of pelvic floor musculature in the treatment of vulvovaginal pain (Glazer, 1995) demonstrated a slightly more than 50 percent cure rate with 83 percent of patients reporting improvement in symptoms; in addition, 80 percent of sexually abstinent patients reported resuming sexual intercourse. Statistically, two main findings emerged. First, there were neither demographic nor SEMG characteristics on initial evaluation that predicted response to this treatment modality. Second, the research showed that only changes in the variability of the resting SEMG signal predicted changes in pain level. This finding confirmed my anecdotal experience that the treatment is essentially an SEMG *stabilizing* program. This paper also concluded that, "The response to this therapy suggests that whatever the initial insult or etiologic factor, vulvar vestibulitis syndrome may be a result of autonomically mediated pain. This mechanism, as a final common pathway for multiple causes of initial vulvar irritation, may explain the lack of consensus on a single causal factor, despite consistency in symptomatology of the syndrome."

A 1996 paper presented evidence that by guiding patients to use the naturally occurring contractions of muscles which spontaneously contract along with the pelvic floor (e.g. internal obturator, lower abdominals, and adductor longus muscles), one could support and enhance the strength and control of the pelvic floor contraction and reduce excess resting tension. Thus the Glazer protocols require that the individualized "testing" of the patient include different positions and the use of different combinations of accessory muscles that enhance, rather than interfere, with the correct use of the pelvic floor muscles.

Two studies concluded that pelvic floor muscle SEMG signals have diagnostic utility. A 1997 study compared 32 vulvar vestibulitis patients with a matched control group of asymptomatic patients and found several SEMG characteristics that reliably differentiated the two groups. Cutoffs for these SEMG characteristics were developed and summarized in this paper, resulting in over 80 percent diagnostic accuracy for vulvodynia using pelvic floor SEMG measures. In 1998, another study compared dysesthetic vulvodynia patients to a matched control group of asymptomatic patients and similar findings were reported, demonstrating

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over 80 percent differential diagnostic accuracy for vulvar dysesthesia using pelvic floor SEMG measures (Glazer, 1998).

A 2000 study demonstrated that, three to five years after successful treatment, 100 percent of patients remained completely asymptomatic with no reports of either vulvar dysesthesia or painful sexual intercourse (Glazer, 2000). Unexpectedly, measures of sexual interest, frequency, and satisfaction did not fully return to pre-symptomatic levels. It was concluded that full functional rehabilitation must include not only pain relief, but psychosexual rehabilitation as well, to achieve both a symptomatic and functionally favorable outcome. (See related article by Glazer, *NVA News*, Fall 1999.)

McKay (2001) studied the effectiveness of pelvic floor SEMG biofeedback in the management of patients with moderate to severe vulvar vestibulitis syndrome and found that almost 85 percent of treated patients reported either negligible or mild pain at the end of the study, with 70 percent resuming sexual activity. Bergeron and colleagues (2001) reported a randomized controlled comparison of vestibulectomy, SEMG biofeedback, and cognitive behavior therapy/pain management in the treatment of dyspareunia (painful sexual intercourse) resulting from vulvar vestibulitis. This study concluded that both medical and psychological treatments can be effective in relieving dyspareunia and recommended a multimodal approach to treatment.

In 2002, with the cooperation of Stanley Marinoff, MD, I presented a technological advancement in the field with a study demonstrating that complete patient evaluation and treatment protocols can be conducted remotely and in real time using a web-enabled SEMG protocol (Glazer, 2002). Currently, my colleagues and I are setting up remote office sites in western Europe that will permit the conduct of live, real time, audio/video enabled patient intake and pelvic floor SEMG evaluation and treatment sessions over the Internet.

Recent research (Hetrick, 2006) compared a group of male patients meeting criteria for National Institutes of Health type IIIa prostatitis, also known as prostatodynia (male chronic pelvic pain), with an asymptomatic matched control group. This study demonstrates differences in intra-anal pelvic floor SEMG readings among the two groups that parallel differences between vulvodynia sufferers and asymptomatic controls. We are designing future studies to evaluate the clinical efficacy of pelvic floor SEMG biofeedback in the treatment of chronic prostatodynia. Most recently, pelvic floor SEMG is being used in a series of studies aimed at selecting patients with vulvar vestibulitis syndrome who may be candidates for pelvic muscle botox injections (Brown, 2006).

Conclusion

Free-form observations of SEMG —with or without direct pelvic muscle palpation—do not comprise an adequate evaluation of vulvodynia patients. Replicable protocols, applied to the patient over time, are necessary to assess patient progress. Similarly, pelvic floor muscle activity level measures alone are not adequate to assess change**.** Variability, speed of muscle contraction and release, and identification of fiber types must all be utilized to ensure that effective rehabilitation of the pelvic floor muscle is taking place. It is also important to remember that one must explore various patient positions, the use of accessory muscles, contraction duration, and a number of repetitions to best achieve the desired SEMG changes which lead to symptomatic benefit.

(*Editor's note: This article was adapted from Glazer, H.I. (2006). Intravaginal surface electromyography in the diagnosis and treatment of vulvovaginal pain disorders.* Biofeedback *34(1), 12-16.)*

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NVA Campaigns for Increased Federal Funding

In April 2006, NVA supporters across the country participated in our second annual Grassroots Advocacy Campaign to raise public awareness and solicit Congressional support for federal funding of vulvodynia research. The campaign aims to convince legislators that their constituents care about the suffering and impaired quality of life caused by vulvodynia. For the second consecutive year, women with vulvodynia and their family members met with both Senate and House health staffers, explaining how the condition impacts their lives and conveying the urgent need for federal research funding.

Chris Veasley, NVA's director of research, spent a day on Capitol Hill meeting with representatives of several key members of Congress serving on health-related committees. She met with the health staffers for Rep. Ralph Regula (R-FL), the chair of the House Health Appropriations Subcommittee, and Senators Arlen Specter (R-PA) and Tom Harkin (D-IA), the chair and ranking minority member, respectively, of the Senate Health Appropriations Subcommittee. She also met with a staffer for Senator Michael Enzi (R-WY), the chair of the Senate Health, Education, Labor and Pensions Committee, and the co-chairs of the Task Force on Women's Health within the House of Representatives' women's caucus, Reps. Tammy Baldwin (D-WI) and Shelley Moore Capito (R-WV). NVA continues to work with representatives of Senators Harkin and Specter to revise the vulvodynia language in the 2007 Senate Appropriations Bill and also requested that Rep. Regula include language promoting federal funding of vulvodynia research in the House Appropriations Bill.

The strength of the language in the Senate and House NIH Appropriations Reports influences the degree to which NIH focuses on, and allocates funding to, vulvodynia research and related initiatives. For example, the FY2006 Congressional report recommended that the Office of Research on Women's Health (ORWH) lead a national educational campaign on vulvodynia, in collaboration with the National Institute of Child Health and Human Development, as well as the NVA and the American College of Obstetricians and Gynecologists. In May, Chris Veasley and Peter Reinecke, consultant to the NVA and formerly Senator Harkin's chief of staff, met with Vivian Pinn, MD, director of ORWH, to discuss the development of an NIH educational campaign for healthcare providers, patients and the public. Dr. Pinn generated many ideas and offered to contact the women's health offices in other government-funded agencies, including the Department of Health and Human Services and the FDA. She plans to develop a comprehensive fact sheet on vulvodynia for NIH and other agencies to disseminate to primary care physicians.

As a major part of advocacy week, women suffering from vulvodynia, their relatives, friends and health care providers, wrote more than 3,500 personal letters or e-mails to members of Congress. More than 400 offices of the 538 Senators and Representatives in the US Congress were contacted. One of the most heartfelt letters sent to Congress came from Erika Eisman of Massachusetts who wrote:

Every moment of my life is affected by this pain. I am 27 years old and have had constant, severe pain in a private area for over 6 years. Can you imagine how having such constant pain would affect the life of your wife or daughter? Several of the numerous doctors I have seen coldly told me that they are not worried because Vulvodynia is "just pain." I was told this last week by a neurologist. Just pain?! Just pain that keeps me locked up when I have so much passion for life. I was a social and active person, yet now I feel homebound, imprisoned and lonely. I am literally and figuratively disabled. I had completed my senior thesis at Brandeis University when the pain began. I want to go on to graduate school. I had so many aspirations before they were halted by the onset of Vulvodynia. I have a long medical history and a team of specialists. I have been my own advocate. I have tried so hard and am still suffering.

Please help my voice be heard and give me a fighting chance for a cure. The only way we'll succeed is by funding research, by nurturing the ideas of the doctors and scientists whose hypotheses have yet to be tested. Only then will we find answers. Only then will I have my life back. The 6 million American women with Vulvodynia will be forever indebted to you for championing our cause.

A longtime NVA advocate, Ann Connell of Colorado, was one of many women across the country who met face-to-face with their representatives. Following her meetings, she wanted to encourage others to speak up and take action. She wrote to other women with

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NVA Honors Dr. Stanley C. Marinoff

In May, the NVA held a tribute dinner to honor Stanley C. Marinoff, MD, for his pioneer clinical work in vulvodynia and for his enduring commitment to vulvodynia patients. Many of his colleagues, family members and friends joined the NVA's executive and medical advisory boards for this special event. Until his recent retirement from clinical practice, Dr. Marinoff was the director of the Center for Vulvovaginal Disorders in Washington, DC and clinical professor of obstetrics and gynecology at George Washington University Medical School. The NVA is grateful to Harriet Silverman of Washington, DC for her generosity in hosting the reception.

L to R: NVA Executive Director Phyllis Mate, Dr. Stanley C. Marinoff, NVA Research Director Christin Veasley

Among the speakers honoring Dr. Marinoff was Maria Turner, MD, a senior clinician in the dermatology branch of the National Cancer Institute, who collaborated with him in the treatment of vulvodynia patients at a time when most gynecologists were unaware of the condition. Beginning in the late 1980s, Drs. Marinoff and Turner wrote several journal articles on the classification and treatment of vulvodynia, significantly raising awareness of the condition in the gynecological community. In her remarks, Dr. Turner, who chaired the first National Institutes of Health conference on vulvodynia, credited him with sparking her interest in vulvodynia research and highlighted the value of a collaborative effort between a gynecologist and a dermatologist in treating vulvodynia and other gynecological conditions. Another colleague who spoke at the event was Ramon Suarez, MD, clinical professor of gynecology and obstetrics at Emory University School of Medicine and chair of District IV of the American College of Obstetricians and Gynecologists (ACOG). He recognized Dr. Marinoff for his many years of service to ACOG and his contributions to the field of women's health. Andrew Goldstein, MD, the current director of the DC Center for Vulvovaginal Disorders, thanked Dr. Marinoff for mentoring him and "for teaching me that every physician learns the most from his or her patients."

NVA Executive Director Phyllis Mate expressed the appreciation of vulvodynia patients, their families and the NVA Board. "Dr. Marinoff, your patients would like to express their gratitude to you for acknowledging that their pain was real and for offering them treatment options at a time when vulvodynia was a little-known disorder," said Mate. She described his role as a "wonderful impetus" behind the creation of the NVA and recalled that he was "the *first* physician to serve on our medical advisory board." Since his retirement, Dr. Marinoff has devoted even more time to advising the NVA, consulting on educational projects for health care professionals, reviewing research grant proposals and participating in important meetings on Capitol Hill.

In November 2005, the NVA Board decided to honor Dr. Marinoff by establishing the *Dr. Stanley C. Marinoff Vulvodynia Career Development Award*. The purpose of the award is to encourage junior faculty to pursue their clinical and/or academic interest in vulvodynia. In presenting the award named in his honor, Dr. Marinoff highlighted the importance of bringing new medical and scientific professionals into the field so they can pursue this line of research or focus on improving patient care. He announced that, "The 14 proposals submitted this year were so impressive that the NVA selected two recipients instead of one," and then proudly introduced Gina Anderson, MD, an award recipient who was able to attend the event. Dr. Anderson is an assistant professor of obstetrics and gynecology and women's health at the University of Medicine and Dentistry of New Jersey-Newark and will use the award to establish a Vulvar Pain Clinic at the New Jersey Medical School in Newark. This clinic will serve a population of predominantly low-income, minority women, currently an unmet need in the community. In addition, the clinic will provide a setting for training medical students and residents in the evaluation and management of patients with vulvar pain conditions. As part of her effort, Dr. Anderson will establish a patient database,

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Neurostimulation

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In this article, I will describe the use of neurostimulation in the treatment of four vulvodynia patients who did not experience adequate pain relief with widely used conservative treatment options. *I must emphasize that using neurostimulation to treat vulvodynia is, at present, an off-label use and not a recognized treatment for the disorder.*

Standard Vulvodynia Treatment

Vulvodynia, a chronically painful condition affecting millions of women, often impairs quality of life and interpersonal relationships. Symptoms typically include burning, stinging, stabbing, irritation, and/or rawness and may be either constant or intermittent. Upon physical examination, the vulva may either appear inflamed or normal. Because observable signs of disease are often absent, vulvodynia can be misdiagnosed and inappropriate treatments prescribed. Many vulvodynia sufferers visit three or more health care providers before obtaining an accurate diagnosis.

Once a diagnosis of vulvodynia is made, there is a wide range of potential treatments. (See Vulvodynia Guideline, *NVA News*, Summer 2005.) Experts acknowledge that no single treatment works well for all, or even most, patients. In most cases, treatment begins with the discontinuation of local irritants, patient instruction on vulvar care and the use of a local anesthetic. For many vulvodynia experts, the first-line of treatment is a low to moderate dose of tricyclic antidepressant, or, less frequently, an anticonvulsant. If vulvar atrophy is present, estrogen cream may be prescribed. Referral to a physical therapist to learn exercises targeting the pelvic floor musculature is common. Nerve blocks with local anesthetic and steroid are occasionally tried. For vulvar vestibulitis, interferon injection therapy may be performed and/or surgery may be indicated. Sometimes, healthcare providers also suggest psychological counseling to deal with the emotional and relationship issues that can accompany the disorder.

As a physician specializing in the treatment of chronic pain, patients are often referred to me because I represent "the last house on the block." In other words, they have most often tried all of the standard treatments that non-pain physicians can offer, without adequate relief. As such, these patients have frequently been told, "There's nothing more that can be done for you." Fortunately, I have not found this to be true in all cases of vulvodynia. While women with mild to moderate pain can often be adequately treated with widely accepted pain-relieving medications, women in severe pain may not be helped by this strategy. Furthermore, some patients who experience pain relief with medication management prefer not to continue taking pain medicine indefinitely.

Neurostimulation for Vulvodynia

Using neurostimulation to treat vulvodynia patients represents a novel use of an existing technology for other severe pain disorders. To date, I have used neurostimulation on four vulvodynia patients with good to excellent results. I believe it may soon become a well-utilized treatment for women with chronic, severe vulvar pain.

The neurostimulator is a small metal case (the smallest of which is 2.2 X 1.8 X 0.4 inches) containing a computer and a battery. In a nutshell, neurostimulation reprograms the pain signal to feel like tingling. Pain is transmitted from the vulva through nerves to the spinal cord and then to the brain. When the pain signal arrives at the brain, it is decoded and perceived as pain. The nerves carrying the pain signal from the affected area, whether it is the vulva, bladder, or pudendal nerve, are the *sacral nerve roots*. We have five sets of these, with one set on each side of the spinal cord. They are numbered S-1, S-2, S-3, S-4 and S-5, and designated as either right or left. In the case of vulvodynia, the pain signals are predominantly carried by the middle three nerves on both sides: S-2, S-3, and S-4.

For vulvodynia patients, I implant the stimulator in the buttock, between the borders of the lower part of the beltline and the upper part of the buttock pocket. This placement has proven to be comfortable and unobtrusive for patients. Then I connect two leads (soft wires with a tiny diameter) to the neurostimulator, one for each side of the vulva. At

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the end of each lead are eight small electrodes, each one smaller than a grain of rice. These electrodes are positioned over the S-2, S-3, and S-4 nerves in the canal inside the bone that attaches from the 5th lumbar vertebra (lowest bone of the spine) to the tailbone or coccyx. No surgery is performed anywhere near the vulva.

The patient controls the neurostimulator with a remote control, somewhat similar to a television remote. Communication with the neurostimulator occurs via radio waves. With the remote, (i) the stimulator can be turned on or off, (ii) the intensity of the stimulation can be adjusted, and (iii) a different program can be selected. The neurostimulator functions by sending electrical signals to the tiny electrodes located over the S-2, S-3, and S-4 nerves. At this point, the signal in the nerves is altered from pain to a different sensation. The neurostimulator's signal, rather than the pain signal, is transmitted to the spinal cord and brain. Although the sensation of the signal varies between patients, most report that the new sensation feels like a pleasant tingling or buzzing. Since the computer can hold many different programs, it is possible to switch from one type of signal to another every few weeks, so the brain doesn't habituate to one type of stimulation and develop resistance to it.

In 2005, rechargeable batteries lasting between five days and several weeks were incorporated into some of these stimulators. The stimulator is recharged by placing a small recharging unit over the skin at the site of the implant. It takes a few hours to recharge the battery, but the unit is portable and unobtrusive, enabling normal activity to continue during this time. Recharging is usually necessary every two to three weeks.

The Trial Period

The first step is to assess whether or not the neurostimulator is appropriate for the patient by testing its efficacy during a seven to ten day trial period. This preliminary procedure is performed on an outpatient basis and our criteria for "success" is a 50 percent or greater reduction in the patient's pain. The first part of the procedure is performed under a fluoroscope, which is basically a real-time X-ray unit. The patient is given an intravenous sedative that puts her to sleep. The lumbar spine is identified and a local anesthetic is applied. Then a tiny incision is made on either side of the spine at about the middle of the lumbar region. A needle is then passed through the incision into the spinal canal. (The spinal canal is continuous with the sacral canal through which the sacral nerves pass.) The needle is specifically located in the epidural space outside of the sac in which the spinal cord and sacral nerves float. A lead is then passed through the needle and into the epidural space. Under fluoroscopy, the lead is then moved down to the sacral canal and positioned so it covers the middle three sacral nerves, which are involved in the transmission of pain signals in vulvodynia patients.

At this point, the patient is awakened from her sedation. Once awake, the leads are connected to a testing computer. Stimulation is then applied through the electrodes over the sacral nerves. In this way, we can be sure that the painful areas are covered by the tingling stimulation. Various programs are then run to fine tune the stimulation. Finally, the leads are stitched to the skin and covered with a sterile dressing. Afterwards, the leads are connected to a portable battery pack-computer that the patient carries with her throughout the course of the trial. Patients are asked to keep a diary of their pain and activities during the trial period.

At the end of the seven to ten day trial period, the patient returns to the office and the leads are removed. The patient's diary is reviewed and together the patient and physician determine whether the neurostimulation has been sufficiently successful. Again, at a minimum, we hope to attain a 50 percent reduction in the patient's pain during the trial period. If a 50 percent reduction has occurred and the patient is satisfied with the degree of pain relief, a permanent implant is scheduled.

Permanent Implant Procedure

The permanent implant procedure is also performed

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on an outpatient basis. The initial procedure is repeated to place and test the electrodes. Then the patient is sedated and an incision is made on the buttock between the borders of the lower part of the beltline and the upper part of the buttock pocket. The incision is slightly deeper than before, in order to create a small pocket (in the fat under the skin) where the neurostimulator will be placed. After the implant, the neurostimulator can be felt beneath the skin, but, except in very thin patients, does not present a noticeable profile. The leads are then tunneled under the skin to the buttock pocket and permanently connected to the neurostimulator. Incisions are then closed and dressed.

Possible Complications

Complications in the testing and implantation of neurostimulators are rare, but as with any invasive procedure, they are possible. If infection does occur, it can either be treated with antibiotics or, if necessary, the stimulator and leads can be removed. In some patients, pain at the neurostimulator implant site may require moving the stimulator to a new location. If the leads migrate after moving the implant, they may have to be repositioned.

Conclusion

Numerous treatments have been used to alleviate the pain of vulvodynia. For patients with severe, intractable pain that has not responded to widely acknowledged conservative treatments, neurostimulation may warrant consideration as a novel treatment option.

(Editor's Note: This article presents a treatment that has been used in a very small number of women with severe, chronic vulvar pain. NVA does not endorse any specific treatment for vulvodynia. Please discuss all treatment options with your health care provider.) ■

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which she hopes will foster clinical research studies among this patient population and lead to collaborative efforts with other academic centers.

The other 2006 recipient of the *Career Development Award* is Catherine Leclair, MD, assistant professor of obstetrics and gynecology and clinician in the vulvar health program at Oregon Health and Science University (OHSU). The obstetrics and gynecology department at OHSU has a history of commitment to vulvodynia patients, most recently demonstrated by their willingness to match the amount of NVA's award to Dr. Leclair. In collaboration with OHSU colleague Martha Goetsch, MD, she will use this award to investigate a hormonal influence in the etiology of vulvar vestibulitis. The study is designed to quantify differences in estrogen and progesterone receptor density and assess accompanying nociceptors (nerve receptors responsible for sensation of pain) and nerve fiber density in vulvar vestibulitis patients. She will (i) compare tissue samples from painful and non-tender sites of the vestibule, and (ii) compare tissue samples from vestibulitis patients to those of an asymptomatic group of women. If Dr. Leclair's study finds a relationship between hormone receptor density and nerve distribution in the vestibule, it would justify further localized tissue research and the development of novel local therapies for vestibulitis patients. ■

If you are interested in applying for the 2007 Career Development Award, please e-mail Chris Veasley at chris@nva.org or call 401-398-0830.

If you would like to make a donation to the Dr. Stanley C. Marinoff Career Development Award (CDA), go to www.nva.org. In the left column, click on Donate; after entering your information, indicate in the appropriate box that your donation is for the CDA Fund. If you prefer, you can mail a check to NVA, PO Box 4491, Silver Spring, MD 20914. Thank you!

Capitol Hill

(from page 6)

vulvodynia in Colorado about the importance of communicating with their legislators:

As part of NVA's second annual advocacy campaign to raise awareness and support for vulvodynia research, my husband and I met with representatives from Senator Allard's and Senator Salazar's offices last week. In each meeting, the representative stressed that the most important action we can take is to get more people to write to their elected officials. We were told that hearing from as few as 50 constituents on any one issue has a huge impact and makes a significant statement.

As a result of Ann's plea, many more women in Colorado contacted their Senators and Representatives. She is now assisting her representatives in drafting a letter from the Colorado Congressional delegation to the Director of the National Institutes of Health, emphasizing the importance of funding vulvodynia research.

Many members of NVA's Chicago support group wrote to Senator Barack Obama (D-IL) and his reply provided details of federal cutbacks in NIH funding:

In the current fiscal year, Congress' budget provided $797 million less to NIH than recommended by the U.S. Senate. It was the smallest increase in NIH funding since 1970. This translates into a reduced number of new research grants, which is why I voted against this level of funding. The President wants to cut the NIH budget for fiscal year 2007 as well.

It is critical that individuals express their disappointment regarding recent cutbacks in NIH funding and that they ask their representatives to *strongly support* an increase in funding in the FY2007 budget. We need women with vulvodynia to contact their elected officials to convey their personal experiences in seeking help. We also need the participation of family members and health care providers in describing the devastating impact vulvodynia has on women's lives. We suggest that patients ask either their health care provider or significant other to accompany them to a meeting. Alternately, we recommend that two or three women with vulvodynia attend a meeting together. It is also not too late to write your legislators. Please take a few minutes of your time and send an email or letter today. You can easily locate contact information for your Senators and Representative by logging onto www.congress.org. (Under 'Write Elected Officials,' type in your zip code and click 'go.' It is that simple.)

The NVA would like to express its gratitude to everyone who took the time to meet with, or write to, their Congressional representatives. If you are interested in meeting with your US Senators and/or Representative in Spring 2007 (either in their state offices or in DC), please contact Chris Veasley, at chris@nva.org or 401-398-0830, for additional information. ■

Biofeedback

(from page 5)

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(*Editor's note: For a complete list of references, e-mail Phyllis Mate at mate@nva.org.*) ■

THE NVA NEEDS YOUR CONTRIBUTION

I WANT TO SUPPORT THE NVA AND RECEIVE MORE INFORMATION ON VULVODYNIA.

Name _____

Address _____

_____

Phone (H) _____ **(O)** _____

E-Mail Address _____

The NVA needs the support of everyone: patients, families, and health care providers.

☐ **$45** ☐ **$75** ☐ **$100** ☐ **Other $** _____

☐ **$75 Health Care Professional**

☐ **Yes, I would like to be contacted by other NVA supporters in my area.**

☐ **No, I do not want to be contacted. Please keep my name confidential.**

Please send your check or money order, payable to NVA, together with your name, address and telephone number to: NVA, P.O. Box 4491, Silver Spring, Md. 20914-4491.

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