National Vulvodynia Association

NVA News

Volume XXI, Issue III Winter 2017

Implant Modalities for Severe Chronic Pain

By Phyllis Mate, M.A.

Ms. Mate, who has a master's degree in clinical psychology, is the editor of NVA News and President of NVA's executive board. From 1996 to 2012, she also served as our executive director.

Women with intermittent or moderate chronic vulvar pain can usually find a combination of treatment measures that reduces their symptoms to a manageable level. This article focuses on pain treatments that can be life-altering for women with severe constant pain that significantly impairs their daily functioning and quality of life.

The two most commonly used implant devices are a spinal cord stimulator and an intrathecal pump. These devices have been used for many chronic pain conditions, including post-herpetic neuralgia, failed back syndrome, interstitial cystitis and vulvodynia. To learn if you're an appropriate candidate for an implanted device, the first step is making an appointment with a pain specialist who does pain-relieving interventions in addition to prescribing medication. He/she will take a careful history, focusing on the pain and any accompanying psychological conditions, e.g., depression. Implanting a pain-relieving device is a minimally invasive procedure that most people have never heard about and may sound scary or overwhelming at first. The reason it's worth investigating is that it can dramatically relieve severe pain

(*See IMPLANTS, page 2*)

Acupuncture for Provoked Localized Vulvodynia

By Lee E. Hullender Rubin, DAOM, LAc, FABORM

Dr. Hullender Rubin, a doctor of acupuncture and oriental medicine, and licensed acupuncturist specializing in reproductive medicine and vulvovaginal pain, practices at the Portland Acupuncture Studio. She is also visiting research faculty at the Oregon Health & Science University in Portland.

Acupuncture, a traditional Chinese medicine modality, is a non-pharmacological and minimally invasive treatment with a good safety profile. It involves the insertion of sterilized, hair-thin filiform needles into specific sites on the body. Controlled studies have shown that acupuncture is an effective treatment for certain chronic

(*See ACUPUNCTURE, page 7*)

IMPLANTS

(from page 1)

and improve quality of life within days.

Intrathecal Pump

Intrathecal drug delivery is used to control chronic pain in patients who have exhausted all other treatment options, including maximum doses of pain-relieving medications. An implanted pump delivers small amounts of medication continuously to the spine, providing enhanced pain relief. It is implanted on one side of the abdomen and has a flexible catheter that travels from the pump into the intrathecal space of the spine (in the middle of the back). Once activated, the computer inside the pump will automatically deliver the prescribed dose of medication at a set rate. During the trial period, the pain specialist administers different medication dosages to assess whether the treatment works and to determine the least amount of medication required to relieve pain.

To make refilling it easy, the pump is placed in a pocket of abdominal tissue close to the skin's surface. A refill kit contains a specified amount of medication and a specialized needle that withdraws any medication left in the pump before the new medication is inserted and the refill date is reset. This procedure takes less than 10 minutes and the only discomfort is the withdrawal of the leftover medication, which only takes a minute. The frequency of pump refills depends on the medication's concentration and the rate of delivery. According to the FDA, the pump must be refilled at least every six months. During the first year or two, the time between refills is shorter, so the doctor can monitor the patient's progress and possible side effects.

Medications that are FDA-approved for use in implanted intrathecal pumps are morphine, baclofen and Prialt. All medications used in implanted intrathecal pumps should be preservative-free. The drug/dosage selection is based on the patient's history of opioid tolerance and side effects, and how effectively it relieves pain during the trial period. Morphine is the most commonly used medication; using intrathecal medication delivery can provide doses that are up to 300 times more potent than oral morphine.

Prialt, a one-of-a-kind medication classified as a neuronal-type calcium channel blocker, is derived from the venom of the cone snail. This medication can be used to treat both nociceptive and neuropathic pain. The most common side effects are dizziness, confusion, nausea and uncontrolled eye movements. Prialt may also cause serious side effects, including cognitive impairment, neuropsychiatric symptoms (e.g., paranoia), meningitis and unconsciousness. Thus, patients using this medication are closely monitored.

Baclofen, a muscle relaxant, was FDA-approved for

(*See IMPLANTS, page 3*)

NVA News

National Vulvodynia Association
P.O. Box 4491, Silver Spring, MD 20914-4491
Tel: (301) 299-0775 Fax: (301) 299-3999
www.nva.org

NVA News is published three times per year.

Editor: Phyllis Mate
Layout: Lisa Goldstein

The National Vulvodynia Association is a nonprofit organization that strives to improve women's quality of life through education, research funding, support and advocacy.

The NVA is not a medical authority and strongly recommends that you consult your own health care provider regarding any course of treatment or medication.

patients with spasticity, a condition in which certain muscles are continually contracted. However, case reports suggest that baclofen can be effective in some patients with chronic pain who do not have spasticity. Baclofen can be intrathecally administered in patients who do not experience pain relief with opioids or used in combination with an intrathecal opioid.

Recent literature supports the use of many other opioid and non-opioid medications for patients who cannot tolerate the FDA-approved medications. For example, some pain specialists have had success using hydromorphone (Dilaudid). In general, there are fewer side effects with intrathecal delivery of opioids than with oral opioids, because the dose is comparatively small and the medication bypasses the stomach.

Selecting a Candidate

The decision to implant an intrathecal pump requires taking a detailed history of the patient's pain and medication use. The pain specialist will specifically want to know what opioid dosages the patient has taken and whether those opioids produced adverse side effects. Prior to implanting an intrathecal pump, the pain specialist will assess whether there are any physical issues that would make placement difficult, e.g., past spinal or abdominal surgery. In order to be considered an appropriate candidate, the patient must experience 50 percent or greater pain reduction during the trial infusion and fulfill the criteria in Table 1. (See right column.) Since a small percentage of patients with intrathecal pumps have had serious complications, the risk-benefit ratio must be carefully weighed.

Possible Complications

For the most part with intrathecal drug delivery, complications and side effects are rare. The pump and catheter are implanted under the skin, so surgical complications, such as infection, spinal fluid leak and headache, are possible. If a patient has an active infection on the day of surgery, the procedure should be postponed. Once the intrathecal pump is implanted, device complications, which may require surgery to correct, may occur. One of the rare, but most serious complications of a malfunctioning pump would be a drug overdose. Other possible complications include the catheter or pump moving within the body or wearing through the skin; the catheter leaking, becoming disconnected or blocked; and the pump stopping because the battery has run out. (Patients are told that the battery has to be replaced every six to seven years.) Additionally, there is a risk of a granuloma (inflammatory mass) forming at the tip of the catheter, which may lead to serious complications. Clearly, intrathecal drug delivery should only be used when the patient, family, and pain specialist agree that it will relieve pain and improve the patient's quality of life.

Table 1
Selecting a Candidate for Intrathecal Medication Delivery

- Ineffective oral analgesia with multiple oral or transcutaneous trials including dose titration
- Intolerable side effects with oral opioids despite opioid rotation
- Functional analgesia during temporary trial infusion
- Psychological stability and reasonable expectations
- Access to care (the patient will return for pump refills/dosage adjustments)
- Patient acceptance

Spinal Cord Stimulation

Although it is not well-established how spinal cord stimulation (SCS) works, it has been proposed that its mechanism of action is consistent with the widely accepted 'gate' theory of pain. According to this theory, repetitive painful sensations open the 'gate' in the spinal cord, thereby transmitting painful impulses to the

(*See IMPLANTS, page 4*)

brain. Spinal cord stimulation is effective because it selectively targets large fiber afferents in the spinal cord, thereby closing the gate without causing any motor effect. The SCS device, similar in size to a cardiac pacemaker, is implanted near a targeted area of the spine and directs mild electrical impulses that interfere with pain messages reaching the brain. The lead or leads are implanted into the epidural space at this targeted area, either percutaneously or with a laminectomy. When the SCS device is activated, the patient feels a tingling sensation over the area of pain, which to some extent, masks the painful sensation. Patients often compare the feeling to the tingling sensation produced by a transcutaneous electrical nerve simulation (TENS) unit. (Although research results are mixed and limited, SCS is covered by Medicare, major commercial health plans and most U.S. workers' compensation plans.)

Selecting a Candidate

Patients who are being considered for SCS should undergo a thorough physical examination and psychological evaluation. (See Table 2 in right column.) They should also have tried medication management, i.e., taken different doses and combinations of medications that only provided minimal relief or caused adverse side effects. The likelihood that SCS will relieve pain and improve function depends on the success of the trial stimulation.

Unlike the intrathecal pump, SCS requires the patient to be involved in its operation. During the trial period and after implantation, the patient has to identify the precise location of the pain, because the tingling sensation must occur exactly where the patient feels pain. Furthermore, the patient plays an active role in managing the pain by using a remote control that can turn the stimulation on and off or adjust the amount of stimulation. The patient's ability to adjust to the tingling sensation and use the hand-held programmer to control the intensity of stimulation is critical to the success of SCS. This implant modality can be a good choice for people with multiple pain areas, because the device can have several leads and the patient can individually adjust the stimulation to each area.

Table 2
Criteria for Appropriate Patient Selection for SCS

- All acceptable and less-invasive treatment options have been exhausted
- A psychiatric evaluation has been conducted and substance abuse is ruled out
- A diagnosis has been established for the pain
- Test trial provides a satisfactory level of pain relief and functional improvement

Spinal cord stimulation is considered to be a useful form of pain relief for patients with failed back syndrome (continuing pain despite operative procedures); chronic intractable pain of the trunk or limbs; and chronic neuropathic pain, e.g., diabetic neuropathy or post-herpetic neuralgia. It is contraindicated if a patient has (i) a pacemaker, (ii) certain medical conditions (e.g., sepsis, bleeding disorder), (iii) an untreated psychological condition, e.g., depression, or (iv) serious drug/behavior problems. Additionally, the patient should show a willingness to use the hand-held remote control.

Possible Complications

The SCS implant is placed under the skin, so surgical complications, such as infection or bleeding, are possible. Once implanted, device complications, such as lead breaking or migration within the intrathecal space, may require surgical replacement of the lead or corrective surgery. Serious adverse events, e.g., injury to the nerve root or spinal cord, are uncommon.

In summary, the advantages of spinal cord stimulation are that it requires minimally invasive surgery, has few side effects, reduces the need for medication and is a

(*See IMPLANTS, page 6*)

In Her Own Words

By Nicole M.

My journey with vulvodynia started over four years ago when I was 28 years old. Prior to that, my life was completely care-free. I was traveling the world, single, and moving up the corporate ladder as a human resources professional. Life was good…until I was prescribed the wrong birth control pill. I had a very adverse reaction that caused me to get my first-ever bacterial vaginal infection. That is when my journey began. I went to several doctors who continued to prescribe antibiotics that didn't help and actually just made me sicker. I was diagnosed with chronic vaginal infections, took many rounds of antibiotics, and had intense pain for over a year. Sitting was almost impossible. Finally, I found an ob/gyn who knew about vulvodynia and diagnosed me with the cotton swab test.

After being diagnosed with vulvodynia, I saw countless doctors looking for help. I had to explain the condition to most of my doctors. Unfortunately, no treatment has helped. It has been a very frustrating, isolating, and painful four years. Thank goodness for my mom who helped me research doctors and different treatments. That is how we found the NVA and I am forever grateful. What I found interesting about vulvodynia is that what works for one person may not work for another. I tried everything -- bladder instillations, acupuncture, physical therapy, antidepressants, topical ointments, vitamin supplements, diets, chiropractic manipulation, and counseling (because I was told it was in my head). I sought help from countless doctors, spending $10,000+ of my savings searching for relief.

Living with vulvodynia has affected every aspect of my life. I used to be an avid cyclist and had to store my bikes, hoping one day to be able to ride again. It affected my career because I couldn't fulfill the demands of my work and have the necessary time off to manage my pain. The pain has taken a toll on my relationships, concentration and problem-solving abilities, and everything is based on how I am feeling at the time.

On a positive note, I have a terrific husband and sweet baby boy (born in February 2017). When I was single, I never thought I'd find someone because I have this condition. Boy, was I wrong! My husband has been so understanding from day one and loves me for who I am. My baby boy has given me new-found purpose and I am more inspired than ever to take my life back. Through the NVA support group in San Diego, a woman told me about a local physician, Dr. Irwin Goldstein. I owe a lot to that woman who came forward to share her experience. In April 2017, I went to see Dr. Goldstein. I am currently under his care and extremely hopeful for the future. He is kind, caring, and passionate about his work. He has given me so much hope.

As a final word, having vulvodynia has taught me a lot about empathy and humility. After years of suffering from severe chronic pain, which completely dictated my life, at times I felt like less of a woman. I understand now that I am the same person I was before having vulvodynia. I know I'm not alone in having this condition and am learning to feel good about myself again. Having supportive friends and family lessens the burden. I am also grateful to the NVA for providing support and resources for women like me.■

Change in E-mail or Mailing Address?

Please be sure to let us know if you have a new e-mail or mailing address. Just send an email to Gigi Brecheen at gigi@nva.org or call her at 301-949-5114. Thanks!

IMPLANTS

(from page 4)

Case Study

Lara developed vulvodynia in her late 20s and suffered from moderate burning and stinging pain for 14 years. During that time she tried high doses of amitriptyline, gabapentin, Effexor, Cymbalta and Lyrica, none of which made an appreciable difference. She also used lidocaine and tried acupuncture. When the pain flared, she was given pudendal blocks with an anesthetic and steroid, which reduced the pain to a manageable level. In her 40s, the vulvar pain became severe and the pudendal blocks no longer worked. She made many trips to the emergency room, where she was given moderately high doses of opioids that relieved the pain for several hours. As the medication wore off, however, the excruciating pain returned. Oral opioids were prescribed, but over time she needed higher and higher doses, until finally they were no longer effective. At this point, Lara realized that she needed a different type of pain doctor and went to a pain clinic that was well-known for using interventional methods. After taking her history, the specialist recommended that she do a trial with an intrathecal pump, which would deliver morphine directly to the spine. He explained to her that there was a good chance of success, because intrathecal delivery was much more powerful than oral opioids.

Lara did a 3-day trial that reduced her pain by 65 percent and the pump was permanently implanted. After a few days of recovery, however, she became violently nauseated and returned to the pain clinic. She told the doctor that it was her first experience with morphine and that nothing else could have caused her nausea and lack of appetite. Having taken oral Dilaudid with minimal side effects, she asked if he could put it in the pump, but he refused. He wanted her to continue using morphine, but she chose the option of flushing the pump and having saline inserted to keep it running. The severe pain returned and Lara contacted another intrathecal pump expert, who agreed to prescribe Dilaudid. Within 24 hours of having the pump filled with a moderate dose of Dilaudid, Lara's excruciating vulvar pain was gone. The only side effect was constipation, which she controls by taking Miralax. Five years later, Lara is still pain-free and has remained on the same medication dosage.

reversible treatment. In some patients, SCS can be so effective that it eliminates the need for pain medication. In others, it reduces the amount of medication needed, thereby alleviating side effects. For example. it can be helpful for people who need high doses of oral opioids to control pain, but experience adverse side effects. If SCS does not produce the expected result, or the patient does not adapt to the tingling sensation, the device and its leads can be removed.

Conclusion

With both the intrathecal pump and SCS, careful patient selection and positive results during the trial period are key to a successful outcome. Once the patient receives an implanted device, monitoring pain relief and side effects is important. The patient is closely linked with the pain clinic and should expect to visit fairly often, especially in the first year. It is very important for the pain specialist to inform the patient's primary care provider about the implant, because it will likely reduce the need for oral pain medication.

(Editor's note: To obtain related references, contact Gigi Brecheen at gigi@nva.org or at 301-949-5114.)■

ACUPUNCTURE

(from page 1)

pain conditions, such as back pain and headaches, but its potential for treating vulvar pain conditions needs further investigation.

Provoked localized vestibulodynia (PLV), chronic vestibular pain without a clear identifiable cause, is typically described as burning pain. Most affected women experience this pain with tampon insertion and sexual intercourse, but in severe cases, pain can be provoked simply by sitting or wearing pants. Thus, PLV can significantly impair a woman's quality of life and sexual confidence. Although the cause is unclear, research has shown that genetic, hormonal, inflammatory, neurological and/or musculoskeletal factors may be involved. Since PLV tends to be a multifaceted pain condition, treatment is often multimodal. Treatment regimens may include a combination of a topical agent, oral medication, pelvic floor physical therapy and cognitive behavior therapy. If symptoms do not improve sufficiently with these treatments, surgical excision of the painful tissue is often recommended.

One common first-line treatment for PLV is a topical anesthetic ointment or cream, such as lidocaine, which provides almost instant temporary relief. Although primarily used before sexual intercourse, two studies of PLV patients found that frequent daily use of lidocaine was associated with a 20 to 50 percent reduction in pain scores. However, a large randomized clinical trial found no significant difference in pain relief in PLV patients using daily lidocaine versus placebo. Clearly, additional effective treatment approaches are needed.

How Does Acupuncture Work?

Acupuncture, a modality within the system of Traditional Chinese Medicine, is frequently used for the treatment of pain, and is a potential therapy for PLV. Our understanding of acupuncture analgesia is still developing, but current theories propose involvement of peripheral, central, and autonomic nervous systems, as well as connective tissue models. Upon insertion, regardless of location or depth, acupuncture needles affect circulating endogenous opioids and their receptors. Acupuncture reduces pain and inflammation, and promotes fibroblast-induced cytoskeletal remodeling. In neuroimaging studies of chronic pain patients who received acupuncture, pain reduction was accompanied by changes in brain neuroplasticity and increased mu-opioid receptor binding. Taken together, these studies suggest acupuncture is a complex treatment intervention affecting multiple systems.

PLV Acupuncture Studies

Preliminary investigations using acupuncture treatment in vulvodynia patients suggest it may benefit women with PLV, but thus far, the quality of these studies has been weak. To date, five small studies have been published. One wait-list control study (including all types of vulvodynia patients with mild to moderate pain) reported modest, but clinically important, pain-reduction with acupuncture treatment. (The outcome measure was the McGill Pain Questionnaire, specifically the domains of sensory and total pain.) In four small uncontrolled studies, acupuncture reduced vulvar pain, improved quality of life and was well-tolerated. Interpretation of these findings is difficult, however, because the quality of the studies varied. Unfortunately, studies of acupuncture in vulvodynia patients use different inclusion criteria and methods of vulvodynia classification, as well as different treatment techniques. Furthermore, they lack adequate control groups and follow-up visits, and use different outcome measures. Clearly, rigorously designed research is essential to assessing the effectiveness of acupuncture as a treatment for PLV.

NVA-Funded Pilot Study

The original objective of my pilot study was to compare the effectiveness of acupuncture to daily lidocaine use in women with PLV, but that design was not approved by the ethics board at our institution. The concern was that one group would receive a first-line

(*See ACUPUNCTURE, page 8*)

ACUPUNCTURE

(from page 7)

treatment (lidocaine) and that the experimental group (acupuncture) might not experience pain relief, causing some patients to suffer. Thus, the protocol was revised to provide lidocaine 5% to both groups and compare the effectiveness of two different types of acupuncture.

The aim of the revised study was to evaluate whether Classical versus Non-Classical Acupuncture was an acceptable low side-effect treatment that would augment pain relief in women using lidocaine for PLV. The Classical Acupuncture group received standardized deep needling with both manual and electrical stimulation. Point selection of up to nine needles per session was based on the patient's traditional Chinese medicine diagnosis. The Non-Classical Acupuncture group received standardized acupuncture consisting of superficial needling without stimulation. For this group, up to four needles were placed away from any acupuncture point, channel or segment thought to influence vulvovaginal pain. (Both acupuncture protocols were physiologically active.)

Our goal was to enroll 30 women, but we were only able to recruit 19 subjects because of our strict inclusion criteria. Five women dropped out for various reasons, e.g., two withdrew because they were sensitive to lidocaine and one was unable to insert a tampon. In future studies, we will modify the inclusion/exclusion criteria to facilitate recruitment.

In the current study, 19 women were randomized to one of the two acupuncture groups and required to attend 18 acupuncture sessions over a 12-week period. All participants were also asked to apply 5% lidocaine cream four times daily. During the intervention period, acupuncture sessions were twice weekly for six weeks and then once weekly for six weeks. A follow-up visit was scheduled 12 weeks after the final treatment. No women withdrew because of the acupuncture itself and there were no serious adverse reactions.

One of the outcome measures was pain with tampon insertion. Women in both treatment groups reported significant pain reduction over the 12-week treatment period. There was no difference in pain relief between the two groups, i.e., both types of acupuncture reduced pain. At the end of treatment, 10 of 14 women reported a 50 percent or greater reduction in pain, and at the follow-up visit, 9 of 14 women reported a 50 percent or greater reduction in pain.

In summary, this pilot study found that combining acupuncture and daily lidocaine use provided moderate pain relief for women with PLV. Most importantly, pain relief was maintained in the majority of participants at the 12-week follow-up visit. Larger controlled studies are clearly needed to verify these findings.

Acknowledgments: Ruth Rowe, MAcOM, LAc, and Alisha Wimberly, MAcOM, LAc contributed to this article.

(Editor's note: To obtain the footnoted version of this article, contact Gigi Brecheen at gigi@nva.org or 301-949-5114.)

Select References

Curran S, Brotto L, Fisher H, et al. The ACTIV study: acupuncture treatment in provoked vestibulodynia. *J Sex Med* 2010;7:981-95.

Danielsson I, Sjoberg I, Ostman C. Acupuncture for the treatment of vulvar vestibulitis: A pilot study. *Acta Obstet Gynecol Scand* 2001;80:437-41.

Guevin F, Steben M, Lepage Y, et al. Vulvodynia and acupuncture. *Med Acupunct* 2005;17:21-3.

Hullender Rubin LE, Mist SD, Schnyer RN, et al. Acupuncture augmentation of lidocaine treatment for provoked, localized vulvodynia. [Abstract]. *J Low Genit Tract Dis* 2017,21:S2-S3.

Powell J, Wojnarowska F. Acupuncture for vulvodynia. *J R Soc Med* 1999;92:579-81.

Schlaeger JM, Xu N, Mejta CL, et al. Acupuncture for the treatment of vulvodynia: a randomized wait-list controlled pilot study. *J Sex Med* 2015;12:1019-27.■