

Topics in PAIN MANAGEMENT

Vol. 28, No. 4

Current Concepts and Treatment Strategies

November 2012

CME ARTICLE

Pain Management of Vulvodynia and Dyspareunia

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Learning Objectives: After participating in this CME activity, the physician should be better able to:

1. Use the current classification system for vulvar pain syndromes.
2. Choose the appropriate treatment option for vulvodynia.
3. Identify the anatomic characteristics of vulvodynia.

Vulvodynia is a condition that is very difficult for women to endure and for health care providers to effectively treat. The pain and discomfort of vulvodynia affects the essential quality of life of women who have this condition. The pain can be continuous or intermittent, often aggravated by activities such as sitting at a desk, bicycle riding, and sexual intercourse (*dyspareunia* is defined as pain at any point during sex). In this review, we present the key differential diagnosis and a suggested algorithm for therapy.

The pain of vulvodynia is often characterized as a burning, stinging, irritation, or as sharp pain that occurs in the vulva, including the labia and entrance to the vagina. It may be constant or intermittent, or it may occur only when the vulva is touched, but vulvodynia is usually defined as a chronic pain syndrome lasting for years. Symptoms may occur at one part or the entire vulvar area.

After reading this article, the practitioner will be able to diagnose vulvar pain syndromes using a classification system and recommend appropriate evidence-based treatments.

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A Historical Perspective on Vulvar Pain Terminology

The first clinical report of vulvar pain was published by Sims¹ in 1861. Often called the father of modern gynecology, Sims

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All faculty and staff in a position to control the content of this CME activity and their spouses/life partners (if any) have disclosed that they have no financial relationships with, or financial interests in, any commercial organizations pertaining to this educational activity.

Dr. Gevirtz has disclosed that use of botulinum toxin A, tricyclic antidepressants (nortriptyline, desipramine), pregabalin, lidocaine topical ointment, and lidocaine/prilocaine cream for treatment of vulvodynia and dyspareunia as discussed in this article has not been approved by the U.S. Food and Drug Administration.

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also pioneered fistula repair surgery and the use of forceps to deliver an infant. Sims described a patient he saw in 1857 with vaginismus who, on further analysis of her history, seemed to have vulvodynia.

In 1874, Thomas² described a patient with “excessive sensibility of the nerves supplying the mucous membrane of some portion of the vulva...” In 1889, Skene³ described a condition characterized by “a supersensitiveness of the vulva. When, however, the examining finger comes in contact with the hyperaesthetic part, the patient complains of pain, which is sometimes so great as to cause her to cry out....”

Similarly, in 1928, Kelly⁴ mentioned that “exquisitely sensitive deep red spots in the mucosa of the hymeneal ring are a fruitful source of dyspareunia.” In 1983, Friedrich³ reported 13 patients with “vestibular adenitis.”

With formation of the International Society for the Study of Vulvovaginal Disease (ISSVD), a definition of vulvar pain was adopted in the 1980s: essential or dysesthetic *vulvodynia*. The term described patients with chronic discomfort, burning, stinging, irritation, and rawness of the vulva.

Fitzpatrick⁴ then conceived the term *vulvar vestibulitis syndrome* to differentiate this problem further. The terminology of continues to evolve. The most recent terminology changes, developed by the ISSVD, were described by Haefner⁵ (Table 1).

Diagnosis

A patient with pain localized to the vestibule has a normal-appearing vulva, other than erythema, which occasionally may appear without a pattern. The erythema tends to be most

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Topics in Pain Management (ISSN 0882-5646) is published monthly by Lippincott Williams & Wilkins, 16522 Hunters Green Parkway, Hagerstown, MD 21740-2116. **Customer Service: Phone (800) 638-3030, Fax (301) 223-2400, or Email customerservice@lww.com.** Visit our website at lww.com.

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Publisher: Randi Davis

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Topics in Pain Management is indexed by SIIC (Sociedad Iberoamericana de Información Científica).

Table 1. International Society for the Study of Vulvovaginal Disease Terminology and Classification of Vulvar Pain (2007)⁵

Term	Classification
Vulvar pain related to a specific disorder	<ol style="list-style-type: none"> 1) Infectious (eg, candidiasis, herpes) 2) Inflammatory (eg, lichen planus, immunobullous disorders) 3) Neoplastic (eg, Paget disease, squamous cell carcinoma) 4) Neurologic (eg, herpes neuralgia, spinal nerve compression)
Vulvodynia	<ol style="list-style-type: none"> 1) Generalized <ol style="list-style-type: none"> a) Provoked (sexual, nonsexual, or both) b) Unprovoked c) Mixed (provoked and unprovoked) 2) Localized (vestibulodynia, clitorodynia, hemivulvodynia, etc) <ol style="list-style-type: none"> a) Provoked (sexual, nonsexual, or both) b) Unprovoked c) Mixed (provoked and unprovoked)

prominent at the duct openings (the Bartholin, Skenes, and vestibular ducts).

The 2 major components in patients with vulvodynia are hyperalgesia (increased response to a stimulus that is normally painful) and allodynia (painful response to a stimulus that is not usually painful, such as light touch). Gentle use of a Q-tip is helpful to define the affected area. Patients often will describe the touch of a cotton ball as extremely painful, like the scraping of a knife.

There are many diseases that can cause vulvar pain (see *sidebar*) but are not considered to be vulvodynia. The key difference is that these diseases are associated with an abnormal appearance of the vulva, and therefore they would not be assigned to the condition known as vulvodynia.

Causes of Vulvodynia

The exact etiology of vulvodynia is unknown. There is most likely not one single cause but a combination of factors that leads to the development of this disease. Etiologic theories proposed include abnormalities of embryologic development, infection, inflammation, genetic/immune factors, and nerve pathways (Table 2).

A systematic approach to therapy is important, and the patient must understand that an individualized, stepwise approach is required (Figure 1). There may be frequent failures along the way, but with patience, some improvement is possible.

Vaginismus

It is important to evaluate whether there is associated vaginismus in patients with vulvodynia, particularly in those with

localized vulvodynia. *Vaginismus* is the involuntary spasm of the pelvic floor muscles closing the vaginal orifice. This spasm can make penetration painful or even impossible. One of the main causes of vaginismus is the anticipation of pain. When painful penetration has been experienced, this pain may be anticipated in further attempts at sexual intercourse. The degree of vaginismus may then further increase the amount of pain, and a vicious circle is established.

Ghazizadeh and Nikzad¹¹ sought to investigate the efficacy of botulinum toxin injection to treat women with moderate and severe vaginismus. They studied 24 women (mean age, 25 years; range, 19–34 years) with vaginismus who had previously failed conservative treatments. Botulinum toxin (150–400 mIU) was injected into the puborectalis muscles in 3 sites on each side of the vagina. Results were as follows:

- Twenty-three patients (95.8%) had vaginal examinations 1 week after procedure that showed little or no vaginismus;
- Eighteen patients (75%) achieved satisfactory intercourse after the first injection;
- Four patients (16.7%) had mild pain;
- One patient was cured after a second injection;
- One patient refused vaginal examination and did not attempt to have coitus; and
- One patient had no coitus as a result of her husband's secondary impotence.

The women were observed for a mean of 12.3 months (range, 2–24 months), and there were no cases of recurrence. The authors concluded: "In refractory cases of vaginismus when conventional therapies have failed, local injection of botulinum toxin can be considered."¹¹

Treatment of Localized Vulvar Pain

There are many treatment regimens for localized vulvodynia (vestibulodynia), but they are not evidence based. Patients often combine a variety of the following regimens.

Oral Medications

Tricyclic antidepressants (eg, nortriptyline) and anticonvulsants (eg, pregabalin) have not been formally studied for the treatment of vulvodynia, but anecdotal reports suggest they have some effectiveness for this troubling condition.

Vulva Care Measures

Practitioners can counsel patients with regard to several steps they can take to reduce or mitigate the pain and discomfort caused by vulvodynia. For example, cotton underwear is recommended for these patients to reduce the irritation that synthetic fabrics can cause. At bedtime, these patients should wear no underwear.

For patients who sweat during exercise, anecdotal reports indicate that wicking underwear has been very helpful. Other tips include the following:

Table 2. Theories on the Etiology of Vulvodynia

Theory	Descriptions
Embryologic analog	It has been noted the bladder and vulva anatomic sites have a common embryologic origin ^{6,7} and therefore are predisposed to similar pathologic responses when challenged (ie, the development of interstitial cystitis in the bladder).
Infection	Candidiasis infection in patient with vestibular pain has been studied. ⁸ The exact association is difficult to determine because many patients report candidiasis infections without verified testing for yeast.
Inflammation	Inflammation (as in vestibulitis) has been excluded from the recent International Society for the Study of Vulvovaginal Disease terminology, since several studies documented a lack of association between the excised tissue and inflammation.
Genetic/immune factors	Goetsch ⁹ was the first researcher to search for a genetic association of localized vulvar pain. He determined that 15% of patients questioned in a brief survey were found to have localized vestibular pain. Of those, more than 30% had a female relative with dyspareunia or tampon intolerance, raising the issue of a genetic predisposition.
Differences in neuropathways	Krantz ¹⁰ examined the nerve characteristics of the vulva and vagina. He demonstrated that there are fewer nerve endings in the vagina as compared with the region of the fourchette, fossa navicularis, and hymeneal ring.

- Avoid vulvar irritants and douching;
- Use mild soap for bathing and avoid applying soap directly to the vulva.;
- If menstrual pads are irritating, 100% cotton pads may be helpful;
- Adequate lubrication for intercourse is strongly recommended (eg, personal lubricants, vitamin E oil, surgical lubricants, gels for vaginal dryness); and
- Cool gel packs applied directly to the site of the pain are also helpful for some patients.

Topical Medications

The use of lubricants should be discussed with the patient. For minor degrees of vulvar pain, some clinicians recommend 5% lidocaine ointment, or lidocaine/prilocaine (EMLA) may be considered for a trial. Topical estrogens have been used for treatment of vulvar pain. Estrogen is applied to the vulva twice daily, with a gradual decrease to daily use, and then to every alternate day.

All the preceding recommendations must be tempered with some skepticism. Foster et al¹² conducted a 12-week randomized, double-blinded, placebo-controlled trial in which 133 vulvodynia-afflicted women were assigned to 1 of 4 treatment arms, as follows:

1. Placebo tablets and placebo cream;
2. Desipramine tablets and placebo cream;
3. Placebo tablets and lidocaine cream; or
4. Desipramine tablets and lidocaine cream

A test for pain scores during insertion of a tampon was selected to test the primary endpoint using a modified intention-to-treat

analysis. Twelve secondary endpoints were also analyzed. At completion of the 12-week randomized phase, women were examined “open label” through 52 weeks’ postrandomization.

The authors demonstrated that all arms reported substantial tampon-test pain reduction:

- 33% reduction: placebo cream–placebo tablet;
- 20% reduction: lidocaine cream–placebo tablet;
- 24% reduction: placebo cream–desipramine tablet; and
- 36% reduction: lidocaine cream–desipramine tablet.

Compared with placebo, the investigators found no significant difference in tampon-test pain reduction with desipramine ($t = 0.90$; $P = 0.37$) or lidocaine ($t = 1.27$; $P = 0.21$). Of the remaining 12 outcome measures, only the Index of Sexual Satisfaction improved with desipramine compared with placebo ($t = -2.81$; $P = 0.006$). During the open-label phase, women undergoing vestibulectomy (surgical excision) reported significantly improved pain relief, as measured by cotton-swab test and the McGill Pain Scale, compared with nonsurgical alternatives.

The authors concluded that oral desipramine and topical lidocaine, as monotherapy or in combination, failed to reduce vulvodynia pain compared with placebo. Placebo or placebo-independent effects are behind the substantial pain improvement seen in all treatment allocations.

Biofeedback and Physical Therapy

Biofeedback^{13–15} and physical therapy^{16,17} are also currently used in the treatment of vulvar pain. These techniques are particularly helpful in vaginismus. Biofeedback aids the patient by helping her develop control over muscle tone to confront and

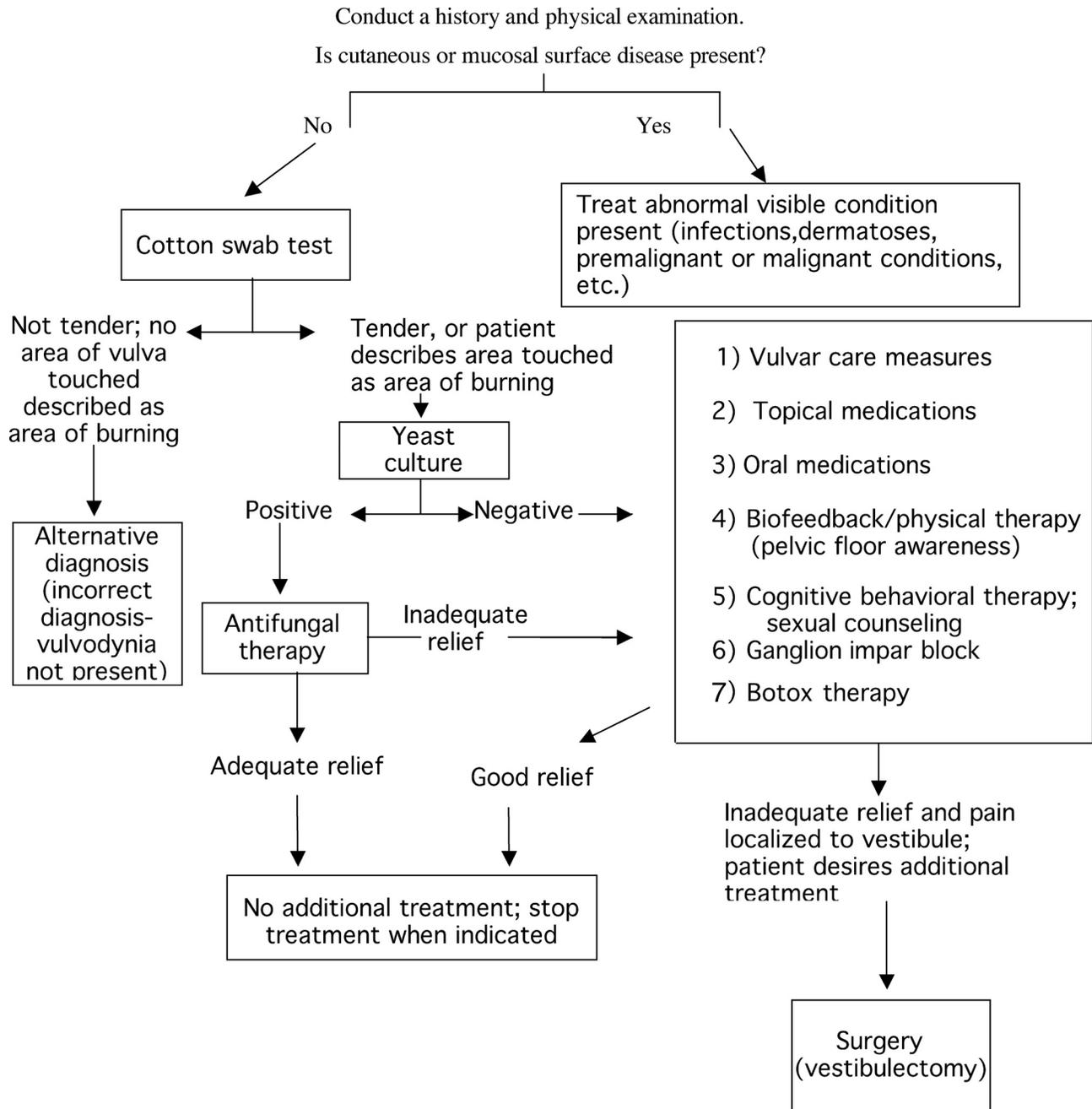


Figure 1. Vulvodynia care algorithm. Modified from Haefner HK, Collins ME, Davis GD, et al. The vulvodynia guideline. *J Low Genit Tract Dis.* 2005;9:40-51.

reduce the pain. In general, patients with vestibular pain have an increased resting tone and a decreased contraction tone after using biofeedback. With the aid of a biofeedback monitor, an individual can view a display of numbers on a meter to assess nerve and muscle tension. In this way, it is possible to develop voluntary control over the painful area and muscle tone.

The time required to learn biofeedback and the frequency of visits will vary with each person but can usually be accomplished within a few weeks. Success rates in the 60% to 80% range have been reported. Physical therapists with expertise in vulvar pain can also be very helpful.

Ganglion Impar Block

A diagnostic ganglion impar block (see *Topics in Pain Management.* 2009;24(10):1-5) may be of use in determining whether there is any sympathetic component to the pain because it provides sympathetic innervation to the area.

Vestibulectomy

Surgical excision¹⁸ of the vulvar vestibule has met with success in up to 80% of reported cases but should be reserved for women with longstanding and localized vestibular pain where other more conservative management has failed.

Diseases That Can Cause Vulvar Pain but Do Not Qualify as a Diagnosis of Vulvodynia

- Aphthous ulcers
- Atrophy of the vaginal mucosa
- Bartholin abscess
- Behçet disease
- Candidiasis
- Chancroid
- Contact dermatitis
- Crohn disease
- Endometriosis
- Herpes infection (simplex or zoster)
- Introitus trauma
- Lichen planus
- Lichen sclerosus
- Metastatic cervical carcinoma
- Pemphigoid
- Pemphigus
- Prolapsed urethra
- Rectovaginal fistula
- Sjogren syndrome
- Syphilis
- Trichomonas
- Vaginal carcinoma (diethylstilbestrol exposure in utero)
- Vulvar carcinoma
- Vulvar intraepithelial neoplasia

Before anesthesia for surgical excision to relieve vulvar pain, in the operating room, the patient should undergo Q-tip testing to outline the areas of pain. Often the incision will need to extend to the opening of Skene ducts onto the vestibule. It is carried down laterally along the Hart line to the perianal skin, and the mucosa should be undermined above the hymeneal ring. The specimen should be excised superior to the hymeneal ring. The vaginal tissue is further undermined and brought down to close the defect, and then the defect is closed in 2 layers using absorbable 3-0 and 4-0 sutures.

Eva et al¹⁹ sought to determine whether vestibulectomy is an effective long-term treatment, to investigate the levels of patient satisfaction in women with localized provoked vulvodynia, and to provide long-term follow-up data from a cohort of women whose short-term success rates have been published previously. They conducted a retrospective case note review of 110 women with localized provoked vulvodynia, along with a follow-up patient questionnaire. Patients were asked to quantify their pain scores before surgery, at 2 months after surgery, and at 1 year after surgery and score their satisfaction levels.

The authors determined that mean pain scores continued to improve throughout the first postoperative year. The mean score was 9.17 preoperatively, 5.24 at 2 months after surgery, and 2.48 at 1 year after surgery. Eighty-three percent of patients said they would recommend the procedure as effective treatment of localized provoked vulvodynia. The overall mean satisfaction score was 7.96, and long-term success seems to be reflected by short-term results.

Eva et al¹⁹ concluded: “Vestibulectomy is an effective long-term treatment for women with provoked localized vulvodynia; the procedure is associated with high levels of patient satisfaction and low complication rates. Short-term success appears to be a good indicator of long-term improvement, and improvement continues throughout the first postoperative year.”

Conclusion

Vulvar pain is a complex disorder that is exasperating to both practitioner and patient. It can be very difficult to treat, with any improvement materializing only after weeks or even months of effort. Spontaneous remission of symptoms has occurred in some women, whereas with others, multiple attempts at medical management have proven unsuccessful in relieving 100% of the symptoms. The treatment of vulvar pain is handicapped by the fact that the underlying cause is unknown in the large majority of cases. It is important to recognize that rapid resolution of symptomatic vulvar pain is unusual, even with appropriate therapy. In addition, no single treatment program is successful in all women. Patience and a systematic approach to managing the pain as well as possible combine to make the best path forward for these unfortunate women. ■

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Report Urges Increase in Addiction Treatment and Physician Education in the Specialty

A 5-year national study on the state of addiction medicine in the United States reported this summer that the US medical system neglects to provide adequate, evidence-based treatment for all but a small percentage of the estimated 16% of the population that suffers from the disease of addiction—a total of 40 million people of ages 12 years and older.

Relevant to Pain Medicine for 2 Reasons

The report's findings should be of interest to pain practitioners for 2 reasons: First, pain management physicians and other professionals working with chronic pain patients must continually be aware of the risks of iatrogenic addiction to opioids and the likelihood that they could be the targets of drug-seeking individuals. However, they must maintain a balanced approach to ensure that they adequately address their patients' pain and provide relief while balancing the risks and the benefits.

Second, the report's assertion of widespread undertreatment, limited access to physicians specializing in addiction, and the sweeping need for greater resources and more evidence-based treatments and consistent standards for quality across the country all sound familiar: Much the same can and has been said recently by panels studying the state of pain care in the United States and worldwide.

No Treatment at All for 90%

According to a press release¹ issued by the study's authors at the National Center on Addiction and Substance Abuse at Columbia University (CASA Columbia) in New York, 90% of people with addiction receive no form of treatment at all, and that there are no national treatment standards to assure a standard quality of care.

The 40 million Americans of ages 12 years and older having addiction involving nicotine, alcohol, or other drugs make up a larger group than the number of Americans with heart conditions, diabetes, or cancer, according to a study released in the summer of 2012. Another 80 million people are considered "risky substance users" of these same substances in ways that threaten health and safety.

The report, *Addiction Medicine: Closing the Gap Between Science and Practice*,¹ reveals that although about 7 in 10 people

with diseases like hypertension, major depression, and diabetes receive treatment, only about 1 in 10 people who need treatment for addiction involving alcohol or other drugs receive it. Of those who do receive treatment, most do not receive anything that approximates evidence-based care, the study reported.

Separate Study Notes Risk of Iatrogenic Addiction or Abuse Even for Cancer Patients

Meanwhile, another report presented at the International Association for the Study of Pain 14th World Congress on Pain² in Milan, Italy, in August suggests that even patients with cancer are not immune from misusing or abusing their narcotic pain medications. The researchers report evidence of addiction, including illicit drug use, double-doctoring, and drug diversion, and they recommend more stringent screening and monitoring for patients with cancer receiving opioid therapy for pain, according to an article published in *Medscape Medical News*.²

Medscape reported that traditionally, cancer patients were not considered at risk for opioid or other substance abuse, given their short life expectancies, according to the study's lead investigator Osama Alabdulhadi, MD, a neuroanesthetist at Dhahran Health Center in Dhahran, Saudi Arabia. He presented his findings on August 28, 2012, at the meeting in Milan.

Alabdulhadi noted that it was a small percentage of the cancer patient population, but that extended life expectancies (due to improved cancer care) have opened a window for a greater risk for substance abuse, he told *Medscape Medical News*. He recommended greater screening, such as by a pain psychologist, which he said can often predict which patients are most at risk for abuse.

In collaboration with the Pain and Symptom Clinic of the London Regional Cancer Program at the University of Western Ontario in London, Ontario, Canada, Alabdulhadi and his group prospectively observed 516 consecutive cancer patients (mean age, 62 years) between 2004 and 2010. The study identified 46 patients (8.9%) who manifested at least 1 risk factor for substance abuse, and 21 patients who manifested 1 or more behaviors "strongly suggestive of addiction," including illicit drug use

(n = 13), ethanol abuse (n = 9), illicit double doctoring (n = 9), and drug diversion (n = 2).²

Addiction Treatment Disconnected From Mainstream Medicine

The CASA Columbia study reported that addiction treatment is largely disconnected from mainstream medical practice. Although a wide range of evidence-based screening, intervention, treatment, and disease management tools and practices exist, they rarely are employed. The report exposes the fact that most medical professionals who should be providing treatment are not sufficiently trained to diagnose or treat addiction, and most of those providing addiction treatment are not medical professionals and are not equipped with the knowledge, skills, or credentials necessary to provide the full range of evidence-based services.

“This report shows that misperceptions about the disease of addiction are undermining medical care,” said Drew Altman, PhD, president of the Henry J. Kaiser Family Foundation, who chaired the report’s National Advisory Commission.

The report documented that although doctors routinely screen for a broad range of health problems such as high blood pressure or high cholesterol, they rarely screen for risky substance use or signs of addiction and instead treat a long list of health problems that result, including accidents, unintended pregnancies, heart disease, cancers, and many other costly conditions, without examining the root cause.

Shortage of Addiction Physicians

According to the report, addiction medicine—much like pain management—is rarely taught in medical school or residency training. With just under 1 million practicing physicians in the United States, only about 1200 are trained in addiction medicine, which presents a barrier for patient access to care, the CASA report concluded.

Some attempts to remedy that shortage have already begun. According to an article in *The Washington Post*,³ the American Board of Addiction Medicine has sponsored a new training program underway at 10 academic medical centers around the country to address an acute shortage of physicians trained in addiction medicine. These training programs offer 1- and 2-year residencies in addiction medicine to physicians who have finished training in another specialty, such as family practice or internal medicine.

The American Board of Addiction Medicine also seeks to have medical treatment of addiction approved as an officially recognized subspecialty in medicine, according to *The Washington Post* article. Currently, only psychiatry has a recognized subspecialty in addiction, called addiction psychiatry.

Few Patients With Addiction Receive Quality Care

The report highlights some inconsistencies between what Americans say they would do and what they actually do, regarding addiction. For example, the CASA Columbia report documented that although almost half of the Americans say they would go to their health care providers if someone close needed help for

addiction, fewer than 6% of all referrals to addiction treatment come from health care professionals.

The report also documented no clearly delineated, consistent, and regulated national standards that stipulate who may provide addiction treatment in the United States. Instead, states and third-party payors have varied standards among them. The report documented that addiction treatment facilities and programs are not adequately regulated or held accountable for providing treatment consistent with medical standards and proven treatment practices.

And then there is the apparent shortage of addiction medicine physicians. Most providers of addiction treatment are addiction counselors who are not required to have any medical training. CASA Columbia’s analysis of minimum state requirements demonstrated that:

- 14 states do not require all addiction counselors to be licensed or certified;
- 6 states do not mandate any educational degree to become credentialed;
- 14 states require only a high school diploma or GED;
- 10 states require an associate’s degree;
- 6 states require a bachelor’s degree; and
- 1 state requires a master’s degree.

Even the physicians and other medical professionals who make up the smallest share of providers of addiction treatment receive little education in addiction science, prevention, and treatment. In fact, CASA Columbia’s report cites other research that determined that of patients who had visited a general medical provider in the past year, only 29% were even asked about alcohol or other drug use.

“Right now there are no accepted national standards for providers of addiction treatment,” said Susan Foster, CASA Columbia’s vice president and director of policy research and analysis.¹ Foster was the principal investigator for the report.

“There simply is no other disease where appropriate medical treatment is not provided by the health care system and where patients instead must turn to a broad range of practitioners largely exempt from medical standards,” Foster said in the press release. “Neglect by the medical profession has resulted in a separate and unrelated system of care that struggles to treat the disease without the resources or knowledge base to keep pace with science and medicine.”¹

A Costly Disease

The CASA Columbia report¹ reveals that addiction and risky use of tobacco, alcohol, and other drugs constitute the largest preventable and most costly health problems facing the United States today, responsible for more than 20% of deaths in the United States, causing or contributing to more than 70 other conditions requiring medical care and a wide range of costly social consequences and accounting for one third of all hospital inpatient costs.

In 2010, only \$28 billion was spent to treat the 40 million people with addiction. In comparison, the United States spent as follows:

- \$44 billion to treat diabetes, which affects 26 million people;
- \$87 billion to treat cancer, which affects 19 million people; and
- \$107 billion to treat heart conditions, which affect 27 million people.

“As our nation struggles to reduce skyrocketing health care costs, this report makes clear that there are few targets for cost savings that are as straightforward as preventing and treating risky substance use and addiction,” Altman said in the press release.¹

Other Notable Findings

Among the reports findings¹ were the following:

- Although addiction is often a chronic disease, treatment typically addresses it as an acute condition and does not include the necessary long-term disease management.
- Public perceptions do not distinguish between risky substance use and the disease of addiction.
- Costs to federal, state, and local governments amount to 11% of total spending; 95 cents of every \$1 pay for the consequences and only 2 cents go to prevention and treatment.

Recommendations

The report offers a comprehensive set of recommendations to overhaul current intervention and treatment approaches and to bring practice in line with the scientific evidence and with the standard of care for other public health and medical conditions.

“It is time for health care practice to catch up with the science,” Foster said. “Failure to do so causes untold human suffering and is a wasteful misuse of taxpayer dollars.”¹

For this study, CASA Columbia conducted a thorough review of more than 7000 publications; in-depth analysis of five national data sets; focus groups and a nationally representative survey of 1,303 adults; state-wide surveys of addiction treatment directors and staff providers in New York State; an online survey of 1,142

members of professional treatment associations involved in addiction care; an online survey of 360 individuals with a history of addiction who are managing the disease; and an in-depth analysis of state and federal governments’ and professional associations’ licensing, certification and accreditation requirements. CASA Columbia also obtained comments and suggestions from 176 leading experts in a broad range of fields relevant to the report.

The report was funded by grants from the Annenberg Foundation; the Diana, Princess of Wales, Memorial Fund and the Franklin Mint; the New York Community Trust; and the Adrian and Jessie Archbold Charitable Trust.

CASA Columbia is a science-based, multidisciplinary organization focused on transforming society’s understanding of and response to the disease of addiction. Founded in 1992 by Joseph A. Califano, Jr, former US Secretary of Health, Education, and Welfare, CASA Columbia assembles the professional skills needed to research, prevent, and treat the disease of addiction from society. CASA Columbia conducts research and uses the scientific findings of others to inform Americans of the economic and social costs of substance use and addiction. The organization aims to reduce the stigma attached to this disease by giving people the tools they need to prevent, treat, and eliminate it.

The report, with key excerpts and recommendations, is available on the CASA website: <http://www.casacolumbia.org/templates/PressReleases.aspx?articleid=680&zoneid=95>. ■

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After Deaths of 3 Children, FDA Warns of Risks of Codeine in Those Who Rapidly Metabolize the Opioid

The US FDA issued a Drug Safety Communication concerning 3 children who died and 1 child who experienced a non-fatal but life-threatening case of respiratory depression after taking the pain reliever codeine. All the 3 had taken the codeine-containing analgesic after tonsillectomy and/or adenoidectomy to treat obstructive sleep apnea syndrome, according to the FDA announcement in August.

According to the FDA, the children received doses of codeine that were within the typical dose range. The 3 children who died

after taking codeine exhibited evidence of being ultrarapid metabolizers.

“The FDA is currently conducting a review of adverse-event reports and other information to determine if there are additional cases of inadvertent overdose or death in children taking codeine, and if these adverse events occur during treatment of other kinds of pain, such as postoperative pain following other types of surgery or procedures,” said Bob Rappaport, MD, director of the Division of Anesthesia, Analgesia, and Addiction

Products in FDA's Center for Drug Evaluation and Research. "The FDA will update the public when more information is available."

Once in the body, codeine is converted to morphine in the liver by an enzyme called cytochrome P450 isoenzyme 2D6 (CYP2D6). Some people metabolize codeine much faster and more completely than others. These people, known as ultrarapid metabolizers, are likely to have higher-than-normal levels of

morphine in their blood after taking codeine, and that higher level can lead to overdose and death.

The estimated frequency of ultrarapid metabolizers is generally 1 to 7 of every 100 people. However, in specific ethnic groups, the frequency may be as high as 28 of every 100 people, according to the FDA. The only way to know if someone is an ultrarapid metabolizer is to do a genetic test. There are FDA-cleared tests to check for ultrarapid metabolism. ■

Class I Recall of CareFusion 303, Alaris Pump Module

The FDA posted a class I recall of the CareFusion 303, Alaris Pump Module, Model 8100 (Figure 1), on August 22, 2012, due to a potential for the pump module door keypad overlay to become loose, peel away, or separate from the door assembly. This malfunction could potentially cause fluid ingress, which could lead to a keypad malfunction, causing the infusion to stop with alarm. When infusion stops, serious injury or death may result.

According to the FDA, the pump module is intended for health care facilities that use infusion for the delivery of fluids, drugs, blood, and blood products using continuous or intermittent delivery through intravenous, intra-arterial, subcutaneous, epidural, enteral, or irrigation of fluid spaces routes of administration. The pump module is used for all ages, including newborns.

CareFusion, of San Diego, California, began notifying its affected customers on July 20, 2012, by sending a letter marked "URGENT: Medical Device Recall Notification," and other facts about the product and the recall. The letter included a summary of affected units and a response card for customers to notify CareFusion of any issues. Customers were asked to visually examine the pump module keypad overlay for obvious signs of overlay separation.

Figure 1 shows an example of a separating keypad overlay. The problem may look different on different pump modules. CareFusion informed customers that they would contact their facilities by phone to schedule a visit to replace the door assembly on their affected pump module.

The FDA recall notice and CareFusion website have a list of affected serial numbers.

Health care professionals and patients are encouraged to report adverse events or adverse effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program:

Complete and submit the report Online: www.fda.gov/MedWatch/report.html. Download form2 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the preaddressed form, or submit by fax to 1-800-FDA-0178.



Figure 1. Alaris Pump Module Model 8100, showing overlay separation. Image courtesy of Carefusion 303.

Coming Soon:

- Deaths of Pain Patients Due to Fungus-Tainted Vials From Compounding Pharmacy
- A Nobel Prize Winner's Contributions to Pain Research

Topics in Pain Management CME Quiz

To earn CME credit, you must read the CME article and complete the quiz and evaluation assessment survey on the enclosed form, answering at least 70% of the quiz questions correctly. **Select the best answer and use a blue or black pen to completely fill in the corresponding box on the enclosed answer form.** Please indicate any name and address changes directly on the answer form. If your name and address do not appear on the answer form, please print that information in the blank space at the top left of the page. Make a photocopy of the completed answer form for your own files and mail the original answer form in the enclosed postage-paid business reply envelope. Your answer form must be received by Lippincott CME Institute by **October 31, 2013**. Only two entries will be considered for credit.

Online quiz instructions: To take the quiz online, **log on to your account at <http://www.topicsinpainmanagement.com>**, and click on the “CME” tab at the top of the page. Then click on “Access the CME activity for this newsletter,” which will take you to the log-in page for CME.lwwnewsletters.com. Enter your **username and password for this screen as follows:** Your **CME username** will be the letters LWW (case sensitive) followed by the 12-digit account number above your name on the paper answer form mailed with your issue. Your **CME password** will be **1234**; this password **may not** be changed. Follow the instructions on the site. You may print your official certificate **immediately**. Please note: Lippincott CME Institute, Inc., **will not** mail certificates to online participants. **Online quizzes expire at 11:59 pm Pacific Standard Time on the due date.**

1. **A patient with vulvodynia will have pain that is localized to the vestibule and a normal-appearing vulva, other than erythema, which occasionally may appear without a temporal pattern.**
 - A. True
 - B. False
2. **The erythema associated with vulvodynia is most prominent at the duct openings (the Bartholin, Skene, and vestibular ducts).**
 - A. True
 - B. False
3. **Diseases that can cause pain in the vulvar area but are not considered to be vulvodynia include all of the following *except***
 - A. lichen sclerosus
 - B. herpes infection (simplex or zoster)
 - C. vulvar intraepithelial neoplasia
 - D. tuberculosis
4. **The bladder and vulva anatomic sites have a common embryologic origin.**
 - A. True
 - B. False
5. **Botulinum toxin has been studied in refractory cases of vaginismus when conventional therapies have failed, and it seems to have some efficacy.**
 - A. True
 - B. False
6. **Anecdotal treatment regimens that have been suggested for patients with localized vulvodynia include all of the following *except***
 - A. wear wicking underwear
 - B. use mild soaps for bathing
 - C. use adequate lubrication for intercourse (eg, personal lubricants, vitamin E oil)
 - D. Pilates
7. **Some practitioners recommend topical treatment with 5% lidocaine ointment or lidocaine/prilocaine for patients with vulvodynia.**
 - A. True
 - B. False
8. **One randomized trial documented that oral desipramine and topical lidocaine, as monotherapy or in combination, failed to reduce vulvodynia pain more than placebo.**
 - A. True
 - B. False
9. **Biofeedback aids the patient by helping her to develop control over muscle tone and to confront and reduce the pain of vulvodynia.**
 - A. True
 - B. False
10. **A diagnostic ganglion impar block may be of use in determining whether there is any sympathetic component to the pain of vulvodynia.**
 - A. True
 - B. False

NEWS IN BRIEF

Nationwide Recall of Hydrocodone Bitartrate/Acetaminophen Tablets

A common hydrocodone/acetaminophen tablet has been the subject of a voluntary nationwide recall by Qualitest, a subsidiary of Endo Health Solutions, working with the FDA.

The announcement by the FDA and Endo came September 10, 2012, that Qualitest/Endo would recall one lot of hydrocodone bitartrate and acetaminophen tablets, USP 10 mg/500 mg.

The FDA website and information from Qualitest also note that it is possible that some tablets from lot C1440512A exceed the weight specification and could be superpotent for the ingredients hydrocodone bitartrate and acetaminophen. The recall includes the following product lot: hydrocodone bitartrate and acetaminophen tablets, USP 10 mg/500 mg, NDC 0603-3888-21, 100 count, lot number C1440512A, expiration date 12/13.

Bottles from the affected lot may contain tablets that have a higher dosage of acetaminophen. This higher dose could result in consumers taking more than the intended acetaminophen dose. Unintentional administration of tablets with increased acetaminophen content could result in liver toxicity, especially in patients on other acetaminophen-containing medications, patients with liver dysfunction, or people who consume more than 3 alcoholic beverages a day.

The product label warns consumers that acetaminophen overdose can potentially cause severe liver damage, at times resulting in liver transplant or death, and that the higher than intended dose of hydrocodone could cause sedation or respiratory depression. No injuries had been reported by September 10, 2012.

The affected lot, C1440512A, was distributed between May 14 and August 3, 2012, to wholesale distributors and retail pharmacies nationwide.

Pharmacists and wholesalers are asked to check their inventories for lot C1440512A, segregate any material from the lot, and to contact MedTurn at 1-800-967-5952 for instructions on product return. Pharmacies that received lot C1440512A will receive a copy of this press release with their recall notification information.

The FDA recommended that pharmacies make their patients and customers aware of this recall. For more information, please contact Qualitest at 1-800-444-4011.

Reports of 4 Serious Burns Prompt Covidien Recall

Covidien announced a voluntary recall of specific production lots of DGPHP radiofrequency ablation (RFA) high-power

single-use grounding pads and Cool-Tip RFA Electrode Kits. The announcement was made August 17, 2012. The company decided to recall specific lots manufactured before August 30, 2011.

Covidien is working with the US FDA and other regulatory authorities on this voluntary recall, according to the FDA website.

The problem seems to be the potential degradation of the foil within the DGPHP grounding pad, according to the FDA. Covidien has received reports of 4 serious injuries that may be related to this product quality issue. The injuries involve burns at the pad sites on the patients.

Customers were notified of this recall by letter on August 6, 2012.

Class I Recall for I-Flow ON-Q Pump With ONDEMAND Bolus Button

The FDA posted a class I recall on August 31, 2012, notifying health care professionals that the I-Flow ON-Q Pump with ONDEMAND Bolus Button may not lock in the down position when depressed, as it should.

The FDA also reported that the orange bolus refill indicator may stay in the lowest position. When this occurs, the patient may receive continuous infusion at a rate greater than expected. As a result, this product may cause serious adverse health consequences, including death. See the FDA recall notice for a listing of affected product numbers.

Manufactured by I-Flow of Lake Forest, California, the On-Q pump with ONDEMAND bolus button is used for continuous and intermittent delivery of medicine, including local anesthetics or narcotics, to surgical wound sites and/or to nearby nerves. The pump can be placed preoperatively and deliver medicine during the procedure/surgery and for postoperative regional anesthesia and pain management.

The FDA reported that I-Flow sent a voluntary recall notice in May 2012 to its customers who purchased the ON-Q pump with ONDEMAND bolus button. Customers should identify all affected products within their inventory and quarantine the affected products.

Health care professionals and patients are encouraged to report adverse events or adverse effects related to the use of these products to the FDA's MedWatch Safety Information and Adverse Event Reporting Program.

Complete and submit the report online: www.fda.gov/MedWatch/report.html. Download form2 or call 1-800-332-1088 to request a reporting form, then complete and return to the address on the preaddressed form, or submit by fax to 1-800-FDA-0178.