



Case Report

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## A Topical Regimen for the Treatment of Provoked Vestibulodynia: Protocol and a Retrospective Case Series

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### Abstract

**Objective:** The primary objective of this study is to describe the effectiveness of a topical treatment protocol for provoked vestibulodynia. The protocol is a 5-7 day trial of 5% lidocaine ointment, followed by a one to two week trial of 0.25% mg desoximetasone and 2% mupirocin ointments in those patients not responding to the lidocaine. As part of the treatment, patients also receive focused training regarding pain site identification and application of the ointments.

**Methods:** A retrospective chart review found 124 patients diagnosed with provoked vestibulodynia between August 2006 and January 2009 who were treated according to the treatment protocol. Extracted from the medical records was reported symptom improvement immediately following treatment and after a minimum 6 months follow-up.

**Results:** The majority of these patients had secondary provoked vestibulodynia with 56.5% reporting symptom(s) duration of greater than 1 year. The rate of positive response to the treatment protocol was 91%. The rate of positive response (90%) continued over a minimum six-month follow-up period, with 96.4% of the positive responders reporting persistent pain relief.

**Conclusions:** Topical overnight 5% lidocaine ointment alone or 5% lidocaine ointment followed by 0.25% mg desoximetasone and 2% mupirocin ointments alleviated symptoms of provoked vestibulodynia over a minimum 6 month follow-up in 90% of the subjects. Accurate patient identification of painful vestibular sites at the periurethral and posterior vestibular areas as well as patient education as to how to apply the ointments is critical component of this therapy.

### Keywords

Provoked vestibulodynia; Lidocaine; Desoximetasone; Mupirocin

### Introduction

Long recognized as a gynecological problem, provoked vestibulodynia also referred to as vulvar vestibulitis was described by Thomas [1] over a century ago. Today, most researchers and clinicians use Friedrich's criteria for identifying the vulvar disorder,

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which include a triad of severe pain upon vestibular touch or attempted vaginal entry, acute pain during cotton swab palpation of the vestibular area and vestibular erythema [2]. More recently, two independent studies have demonstrated vestibular erythema to be a less reliable criterion [3,4]. Gross examination may show erythema but histological evaluation does not confirm infection, neoplasia, or neurological disorders [5,6,7]. Provoked vestibulodynia had been viewed as a subcategory of chronic vulvar pain effecting up to 16 % of women in the general population [8], but a recent re-evaluation of pain definitions suggests that it should be considered a "dysfunctional pain induced by exposure to acute physical or psychological precipitating events in the presence of a predisposition to produce abnormal central sensitization" [7,9]. Symptoms do not appear to differ between pre- and post- menopausal women [10] or with sexual experience [11]. The lifetime prevalence of this condition may be as high as 28% and is recognized as the most frequent cause of dyspareunia in premenopausal women [2,12].

Provoked vestibulodynia can have a seriously negative impact in a woman's life, affecting intimate relationships as well as consuming healthcare dollars as the patient seeks to resolve an unrelenting and persistent problem. Women with vulvar pain syndromes often seek help from multiple clinicians prior to being diagnosed [13]. However, once diagnosed, there is no generally accepted treatment method. Clinicians often try several different therapies until one appears to alleviate symptoms. A 2009 review [14] of treatment options identified 38 studies of which 14 use conservative treatments including topical applications, systemic medications, and injections, and a subsequent review evaluating these options concluded that there is little evidence that non-surgical treatments were effective beyond a placebo effect [15].

When all else fails, surgical excision of the vestibule is performed, and this therapeutic option has shown some efficacy [15-17]. However, the effectiveness of vestibulectomy has been found to diminish up to 40 to 60% with longer observation [16]. Surgery is also the most invasive and expensive therapeutic option for provoked vestibulodynia. There are few treatment options that are relatively inexpensive and non-invasive which are also highly effective in alleviating pain over the longer term.

Over the past several years, we have developed in our urogynecological practice a topical regimen for the treatment of provoked vestibulodynia that appears to be highly effective and is well tolerated by patients. The purpose of this report is to describe this treatment regimen and to present clinical data demonstrating its initial and longer term (minimum six month follow-up) effectiveness.

### Materials and Methods

#### Retrospective chart review

A retrospective chart review was conducted on all patients seen in our practice with a diagnosis of provoked vestibulodynia between August 2006 and January 2009. The Institutional Review Board at United Health Services Hospitals, Inc., Johnson City, New York, approved the project. All subjects were evaluated and treated by a single practitioner.

The following criteria were applied for patient inclusion in this study: 1) diagnosis of provoked vestibulodynia based on Friedrich's

criteria, including vulvar erythema in the absence of other pathology, pain upon vestibular touch/entry, and tenderness with localized pressure to the vestibule and 2) having received the treatment regimen according to the protocol outlined below. Patients who had other types of vulvitis or vaginitis, including vaginal and fungal infections were excluded. However, a few patients with a co-diagnosis of lichen sclerosus were included because the area involved by lichen sclerosus was separate from the vestibular area and discrete burning reproducible pinpoint pain could be elicited with the use of a cotton swab test at three of the four individual sites. Patients with a history of malignancy within the past five years and patients with a history of hypersensitivity or allergic reaction to topical lidocaine and/or mupirocin were also excluded. Patients were also excluded if they had received pelvic radiation therapy. Finally, patients on oral contraceptives or taking hormone replacement therapy (HRT) were included. Following the review, a total of 127 patients met inclusion criteria. Of these, three subjects were excluded because of missing data. Thus, the total number of subjects available for evaluation was 124.

All of the final subjects were contacted by phone between June and August 2009 to gather information on long-term treatment outcomes. Follow-up information was obtained on 122 of the 124 patients.

### Treatment protocol

After the diagnosis of provoked vestibulodynia was confirmed, the initial treatment was initiated consisting of nightly application of a 5% lidocaine ointment. All subjects were instructed to saturate a cotton ball with the lidocaine ointment and insert the saturated ball inside the vaginal opening at a depth of about the first knuckle at bedtime, similar to the procedure described by Zolnoun et al. [13]. The cotton ball was to be left in place for a minimum of two hours and preferably overnight. All subjects were instructed to repeat this treatment for five to seven consecutive days. No other medications or dietary modifications were initiated. All subjects also receive a diagram of the vulvar area and written patient information "Is it Vulvar Vestibulitis?" [14]. This article provides a thorough and understandable discussion of the symptoms and manifestations of provoked vestibulodynia

A return visit was scheduled for two weeks after the initial visit (one week after the cessation of the lidocaine treatment) to evaluate the effectiveness of this initial treatment. At the return visit, subjects were prescribed 0.25% mg desoximetasone ointment and 2% mupirocin ointment if symptoms persisted. Subjects with persistent symptoms were also instructed in the use and application of these ointments through fingertip application to the involved sites. Subjects were told to palpate inside the introitus to the depth of their first knuckle, using the midline of the pubic bone as a referent for identifying the sites of tenderness. They were taught to palpate to the right and left as well as slightly in front of or behind the pubic bone. Instructions were given verbally and in writing. Once the areas of tenderness were identified, subjects were instructed to apply both ointments three times per day, once in the morning, once at midday and once in the evening, massaging them into the affected posterior vestibular and periurethral gland sites. A diagram of the introitus was also reviewed in detail with each patient in order to reinforce where to apply the ointments. No other oral medications or dietary modifications were initiated. Subjects were instructed to apply the ointments for one week and return for follow-up two weeks after the second visit (one week after cessation of the desoximetasone and mupirocin ointments). Subjects with persistent symptoms at this second follow-

up visit were again shown how to identify and palpate affected sites in order to ensure proper application of therapy. A third follow-up visit was scheduled two weeks after this second follow-up (again after one week of the desoximetasone and mupirocin ointments). Surgery was discussed at that point with those subjects for whom the treatment continued to be ineffective. Finally, in case of a pain relapse, subjects were instructed to reapply the last ointment regimen that alleviated the pain initially.

### Improvement criteria

Patient improvement with treatment was determined by evaluation of the persistence of symptoms, which was reported by the patient on a 4-point scale (no improvement, some improvement, reasonable improvement, and complete improvement). Treatment assessed as reasonable or complete were considered successful for this assessment. Improvement was evaluated at the completion of the initial lidocaine treatment, at the completion of the desoximetasone/mupirocin treatment for patients when lidocaine alone was unsuccessful and again during follow-up. The proportion of patients whose treatment was considered successful was calculated at each juncture.

### Results

Table 1 lists selected characteristics of the patients included in the chart review. As indicated, the average age of the women was 48.6 years, with a range of 16 to 89 years. The average parity of the subjects was 1.9, with 26.2% being nulliparous. The sample was overwhelmingly white (96.7%) with a little over half (57.0%) being married. All total, about a third of the women were on some sort of hormonal therapy; 30.4% of the premenopausal women were taking oral contraceptives, while 34.4% of the post-menopausal women were on HRT. The majority of patients were referred with either dyspareunia (34.7%) or chronic urinary tract infections (28.2%) as their primary presenting diagnosis, and a majority (56.5%) had experienced symptoms for longer than one year. At the initial visit, patients were asked how often they avoided sexual intercourse due to vaginal pain (occasionally, often, or no sex at all). Virtually all the patients (99.2%) reported that they avoided sexual intercourse to some extent. due to vaginal pain. The length of follow-up from last treatment ranged from 6 to 24 months.

The proportion of patients who responded to lidocaine alone and those who responded to the two-phase regimen after initial treatment and at follow-up were calculated. A total of 37.1% (46/124) of the patients initially responded to lidocaine alone. Of these, 17 (37%) had a relapse of symptoms. These patients were instructed to reapply the ointment according to the initial protocol. In all cases, the reapplication successfully resolved the symptoms.

The switch to desoximetasone and mupirocin in those patients where lidocaine was not effective increased the proportion of patients who responded to treatment to 91% (113/124). Of these patients, 20 experienced a relapse of symptoms. These patients, like those who responded to lidocaine alone, were also instructed to reapply the ointments following the initial desoximetasone/mupirocin protocol. In all cases, the reapplication successfully resolved the symptoms.

At follow-up, the treatment success rates persisted, not only for patients who received lidocaine only (remaining 37%, 45/122) but also for those who received the second phase of the regimen (90%) (110/122) (an additional 65 successes). Interestingly, of the two patients lost to follow-up, one reported a positive response to the initial treatment and the other did not.

**Table 1:** Selected characteristics of the patients evaluated.

	N	Mean (Range) or Percentage
<b>Age (years)</b>	124	48.6 (16-89)
<b>Parity</b>	122	1.9 (0-7)
Nulliparous		26.2%
<b>Race</b>	123	
White		96.7%
Other		3.3%
<b>Married</b>	121	57.0%
<b>Education Level</b>	124	
Less than High School		8.9%
High School Graduate		41.1%
Some College		19.4%
College Graduate		12.1%
Post-Graduate		18.5%
<b>Premenopausal</b>	122	46.7%
<b>Hormonal Therapy</b>	120	32.5%
<b>Oral Contraceptives (pre-menopause)</b>	56*	30.4%
<b>HRT (post-menopause)</b>	64*	34.4%
<b>Primary Presenting Diagnosis</b>	124	
Dyspareunia		34.7%
Chronic Urinary Tract Infections		28.2%
Dysuria		17.7%
Interstitial Cystitis		15.3%
Vestibulitis		1.6%
Urinary Frequency		1.6%
Chronic Yeast Infection		0.8%
<b>Duration of Symptoms</b>	124	
0-3 Months		13.7%
6 Months		18.5%
1 year		11.3%
More than 1 year		56.5%
<b>Number of Prior Physicians Seen</b>	123	
None		0.8%
One		35.8%
Two		42.3%
Three		19.5%
Four		1.6%
<b>Pain Effect on Sexual Intercourse</b>	124	
No Avoidance		0.8%
Avoid Occasionally		14.5%
Avoid Frequently		46.0%
Avoid Completely		38.7%

**Note:** \*Total number of women pre- or post- menopause.

Of the 110 patients who reported being symptom-free for at least six months after the last application, 109 or 99.1% remained symptom free long term. Thus, 96.4% (109/113) of the initial positive responders who had follow-up persisted in their positive response after at least six months from their last treatment. One patient who did not respond initially felt symptomatically improved over time. There was no difference between the long-term rate of positive response in patients who responded to lidocaine only (45/46 or 97.8%) and those who continued with the 0.25% mg desoximetasone ointment and 2% mupirocin ointment (64/67 or 95.5%).

Finally, in assessing the ease of implementation of the protocol, we found chart notes indicating that twenty eight (28) patients

were unable to identify correctly the sites of inflammation without physical demonstration. These patients, however, were able to apply the ointments successfully after more focused, directed physical instruction using the diagram as described in the treatment protocol.

## Discussion

After initial treatment and at a minimum 6 month follow-up, more than 90% of patients presenting with provoked vestibulodynia had either reasonable improvement or completely resolved symptoms after a regimen of 5% lidocaine ointment alone or 5% lidocaine ointment followed by 0.25% mg desoximetasone and 2% mupirocin ointment. Importantly, 96.4% of the patients who responded to the initial treatment experienced extended pain relief, supporting the effectiveness of the treatment. Interestingly, just over a third of the patients responded to lidocaine alone, which was consistent with the results of a recent clinical trial but not with the results of another observational study, which showed a higher success rate (60%) when lidocaine was used over a longer time frame [18]. The mechanism of action of lidocaine for treatment of provoked vestibulodynia is not fully understood. There is some evidence suggesting both inflammatory and/or infectious etiology [19,20].

In an exploratory case-control study, Sarma and co-workers [21] found that a history of bacterial vaginosis, yeast infections, and human papilloma-virus were strongly associated with provoked vestibulodynia. From their findings, they speculated that the symptoms might have an infectious origin. More recently, Babula and co-workers [22] evaluated whether women with provoked vestibulodynia had a single nucleotide polymorphism at codon 54 in the gene that produces mannose-binding lectin (MBL), a component of the innate immune system that is involved in the defense against fungal, bacterial, and viral pathogens. Studies have shown that women who carry the MBL\*B polymorphism have reduced circulating and vaginal MBL levels and are more susceptible to infections and proinflammatory immune responses [22]. Babula and co-workers [22] found that this polymorphism was significantly more prevalent in women with provoked vestibulodynia, suggesting that a microbial infection possibly precipitated by the exposure to semen might potentially serve as the initial trigger for the onset of symptoms in susceptible women. However, they also noted that it was possible that other biologic processes might be involved in the development of the syndrome. More recent in vitro studies [23,24] suggest that a fibroblast-mediated proinflammatory response to the yeast pathogen *Candida albicans* may contribute to the induction of pain in provoked vestibulodynia. A recent review of the role of inflammation in the etiology of provoked vestibulodynia also provides some evidence that immunological abnormalities involving cytokines and neurokinins may induce inflammation in vestibular tissues [25].

Several studies have shown that lidocaine has both anti-inflammatory and antibacterial effects [26-30]. Specifically, lidocaine is antibacterial for both gram-negative and gram-positive bacteria. In gram-negative bacteria such as *E. coli*, *Salmonella typhimurium*, and *Pseudomonas aeruginosa*, lidocaine appears to act synergistically with antibiotics by depolarizing the bacterial cell membranes and increasing cell membrane permeability [26]. Kirk and co-workers have found that lidocaine in a concentration of 0.05% is bacteriostatic for *S. aureus* [27]. In addition, Gajraj and co-workers reported that all gram-positive organisms tested, including *S. aureus* had significantly lower colony counts in 0.05% or higher concentrations of lidocaine, and all gram-negative organisms tested had significantly lower colony counts in concentrations of 0.2% or higher [28]. Other in vitro

evidence indicates that lidocaine is not only bacteriostatic but actually bactericidal for organisms isolated from skin lesions [29], and an IV infusion of lidocaine inhibited granulocyte adherence and prevented granulocyte delivery to inflammatory sites in rabbits with aseptic peritonitis [30].

Assuming that symptoms are produced by a combination of inflammation and bacteria, it is reasonable to also assume that additional response may be obtained with the use of an anti-inflammatory agent together with an antibiotic in patients not responding to lidocaine alone. We chose 0.25% mg desoximetasone ointment as anti-inflammatory agent because an earlier study [31] had shown that this topical corticosteroid was effective in alleviating vestibulodynia symptoms in about a third of the patients treated. We chose mupirocin ointment for the antibacterial agent because it is active against a wide range of gram-positive bacteria including methicillin-resistant *S. aureus* (MRSA). It is also active against certain gram-negative bacteria. Mupirocin inhibits bacterial protein synthesis by binding reversibly to bacterial isoleucyl transfer-RNA synthetase. Due to this unique mode of action, mupirocin demonstrates no in vitro cross-resistance with other classes of antimicrobial agents. Mupirocin has been shown to be active against most strains of *S. aureus* and *Strep pyogenes* as well as against most strains of *Staph epidermidis* and *Staph sphyoticus*. A short treatment course with mupirocin in other parts of the body has demonstrated long-term effectiveness. Doebbeling and co-workers reported for example that a single dose of mupirocin administered intranasally was effective in reducing nasal *S. aureus* for up to 1 year [32]. Since we did not obtain cultures from affected areas in patients, we cannot add information in support of an infective etiology.

We found that our treatment regimen is highly dependent on good patient education and instructions. Specifically, those patients who require the use of desoximetasone and mupirocin require very careful instructions on how to apply these ointments. Many women are unfamiliar with their own anatomy. In addition, we found that women who experience pain and soreness in the vaginal/vulvar area are not inclined to touch themselves. We think it is critical to teach patients to identify clearly the tender vestibular and periurethral sites in order to assure effective treatment. Nonetheless, this treatment is topical, relatively inexpensive when compared to other alternatives such as surgery, and offers a good first line treatment option, particularly for patients with limited incomes.

A weakness of this study is that we did not obtain a pretreatment pain scale, nor did we use a validated tool for pain assessment. There are also other inherent biases related to patient recall. Since this is a retrospective review, the provider was not blinded to the treatment. Thus, an area for further study would be a prospective randomized trial of lidocaine alone versus combination of desoximetasone and mupirocin, or of the sequential combination of lidocaine then desoximetasone/ mupirocin similar to the trial conducted by Foster and co-workers. Further, there are also several studies that demonstrate a correlation or at least a co-existence between interstitial cystitis and provoked vestibulodynia with reported percentages varying from 12% to 68% [33,34]. The hypothesis that vestibulodynia is a contributing etiological factor in patients presenting with symptoms of chronic UTI unrelieved with antibiotic could also be tested.

In summary, we have found that a therapy of 5% lidocaine ointment alone or 5% lidocaine ointment followed by 0.25% mg desoximetasone and 2% mupirocin ointment can be highly

effective in the treatment of provoked vestibulodynia and should be considered as a first line treatment option for women diagnosed with this condition.

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