

# The ACTIV Study: Acupuncture Treatment in Provoked Vestibulodynia

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## ABSTRACT

**Introduction.** Provoked vestibulodynia (PVD) is a distressing genital pain condition affecting 12% of women. Treatment modalities vary and although vestibulectomy has the highest efficacy rates, it is usually not a first-line option. Acupuncture has a long history in the traditional Chinese medicine (TCM) system and operates on the premise that pain results from the blockage or imbalance of important channels. The main principle of treatment is to move Qi and blood to cease genital pain.

**Aim.** To explore effect sizes and feasibility in a pilot study of acupuncture for women with PVD.

**Methods.** Eight women with PVD (mean age 30 years) underwent 10 1-hour acupuncture sessions. Specific placement of the needles depended on the woman's individual TCM diagnosis. TCM practitioners made qualitative notes on participants' feedback after each session.

**Main Outcome Measures.** Self-reported pain (investigator-developed), pain-associated cognitions (Pain Catastrophizing Scale [PCS], Pain Vigilance and Awareness Questionnaire), and sexual response (Female Sexual Function Index) were measured before and after treatment sessions 5 and 10. Qualitative analyses of TCM practitioner notes were performed along with one in-depth case report on the experience of a participant.

**Results.** A repeated measures analysis of variance revealed significant decreases in pain with manual genital stimulation and helplessness on the PCS. An examination of effect sizes also revealed strong (though nonsignificant) effects for improved ability to have intercourse and sexual desire. Qualitative analyses were overall more positive and revealed an improvement in perceived sexual health, reduced pain, and improved mental well-being in the majority of participants.

**Conclusions.** Effect sizes and qualitative analyses of practitioner-initiated interviews showed overall positive effects of acupuncture, but there were statistically significant improvements only in pain with manual genital stimulation and helplessness. These findings require replication in a larger, controlled trial before any definitive conclusions on the efficacy of acupuncture for PVD can be made. **Curran S, Brotto LA, Fisher H, Knudson G, and Cohen T. The ACTIV study: Acupuncture treatment in provoked vestibulodynia. J Sex Med 2010;7:981–995.**

**Key Words.** Provoked Vestibulodynia; Vulvodynia; Vulvar Pain; Genital Pain; Acupuncture; Traditional Chinese Medicine; Eastern Approaches

## Introduction

Provoked vestibulodynia (PVD) is a chronic, persistent clinical syndrome characterized by severe pain upon touch of the vulvar vestibule and/or attempted vaginal entry [1]. It is generally diagnosed through the use of a standard gynecological

cotton swab test, where a cotton swab is applied along Hart's line and around the vestibule in a clock-like fashion. The qualities of pain reported when the vestibule is palpated include: tearing, cutting, burning, and stabbing. PVD has a high prevalence, with reported rates of 12% in the general population [2] and approximately 15% in

general gynecological practice [3]. A large study in adolescent women (aged 12–19 years) found that among young women with genital pain complaints lasting 6 months or more, the prevalence of dyspareunia was 20% [4]. Because PVD appears most prevalent in young women, it can have lasting effects on sexual identity and possibly on sexual self-confidence. It is also significantly associated with somatic health including urinary tract infections (odds ratio [OR] = 6.15), yeast infections (OR = 4.24), chronic fatigue syndrome (OR = 2.78), fibromyalgia (OR = 2.15), depression (OR = 2.99), and irritable bowel syndrome (OR = 1.86) [5]. In addition, the generalized pain of PVD affects daily living and has a severe negative impact on sexual functioning [6–9].

Current standards of care for PVD include the use of oral and/or topical medications, pelvic floor physiotherapy with biofeedback, psychological treatment, and surgery. Among these, prospective nonrandomized trials of vestibulectomy have shown the highest rates of improvement ranging from 61% to 83% [10–13] and a randomized controlled trial showing near complete or complete pain improvement in 68% [14]; however, vestibulectomy is typically reserved as a last-resort treatment option for very carefully selected patients [15]. As reviewed by Landry and colleagues, topical formulations have shown less impressive improvements compared with surgery [16]. For example, approximately 57% of women reported a moderate improvement with topical lidocaine, 44% had complete improvement with topical ketoconazole, and 54% showed a positive response to topical cromolyn. However, given the large placebo response [17], randomized trials in this area are sorely needed. Oral medications have shown similar efficacy rates to the oral preparations ranging from no response to a 60% response with amitriptyline (as reviewed by Landry et al [16]). Because of the known hypertonicity of the pelvic floor in women with PVD [18], physiotherapy (with biofeedback) is a frequent adjunct of treatment and has shown efficacy rates ranging from 52% for physiotherapy [19] to 83% for biofeedback alone [20], with improved outcomes not only on pain but also on sexual response [21]. A psychological intervention focusing on cognitive-behavioral skills has shown improvements in 21–28% of patients [14] with no deterioration of improvement in sexual function and continued improvement in genital pain when assessed 2.5 years later [22]. Overall, research on new, effective methods of pain and distress reduction for women

with PVD is sorely needed given the negative side effects of oral medications [23] and the fact that surgery is typically a last-resort option [15,16].

Acupuncture is one of the treatment modalities within the medical system of traditional Chinese medicine (TCM). It has been practiced for thousands of years in China and other Asian countries, and is gaining acceptance within the Western medical community. According to the TCM theory, there are more than 2,000 acupuncture points on the human body connecting 12 main and eight secondary “meridians” or channels. Pain and disease are the result of these channels becoming blocked and/or imbalanced. To restore healthy energy and balance, thin, sterile needles are inserted into specific points along these meridians. Each acupoint is then activated by applying very small rotations and thrusting movements of the needle to elicit “de chi”—a sensation of numbness and fullness in the area. Because the liver, kidney, and spleen channels pass through the genital region [24], TCM theory presumes that any combination of these channels are affected in women with PVD. The main principle of treatment is to move Qi and blood to stop pain and to unblock meridians. Table 1 lists the specific areas of imbalance presumed to play a role in contributing to the pain of PVD [24] and the associated acupuncture principles of treatment. In China, acupuncture is typically administered daily, though in North America, it is more customary to have one to two sessions per week.

Western medicine’s view is that the placement of acupuncture needles at specific pain points releases endorphins and opioids, the body’s natural painkillers. Acupuncture is also purported to improve immune and central nervous system function. According to the National Institutes of Health’s National Center for Complementary and Alternative Medicine [25,26], there is also evidence that stimulating acupuncture points enables electromagnetic signals from the brain to be relayed at a greater rate than under normal conditions. This may increase the flow of healing or pain-killing natural chemicals to injured areas.

Reviews of acupuncture treatment studies (in patients with chemotherapy-induced nausea and vomiting, postoperative dental pain, addiction, stroke rehabilitation, headache, menstrual cramps, tennis elbow, fibromyalgia, myofascial pain, osteoarthritis, low back pain, carpal tunnel syndrome, duodenal ulcers, and asthma, for example) conclude that there is strong evidence to support that acupuncture provides pain relief, often where

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