

Ph.D. thesis by Christina Damsted Petersen, MD

Sexological Clinic, Psychiatric Centre Copenhagen
and
Department of Gynecology, Juliane Marie Centre
Rigshospitalet University Hospital
Faculty of Health Sciences,
University of Copenhagen, Denmark

Title:

What Predicts Diagnosis, Pain Relief and Sexuality in Women with Vulvodynia? Botox – a new treatment for vulvodynia?

Abstract:

The Ph.D. thesis originated from the Sexological Clinic, Psychiatric Centre, Rigshospitalet and the department of Gynecology, Juliane Marie Center, Rigshospitalet University Hospital in Copenhagen, Denmark.

The purposes of the Ph.D. study were to obtain more knowledge on the physiologic, sexual and psychological aspects of vulvodynia and to evaluate the effect of a new treatment on vulvodynia.

Vulvodyn is defined by the ISSVD (International Society for the Study of Vulvar Disease) as "vulvar discomfort, characterized by stinging, burning, irritation or rawness" in the absence of relevant visible findings or a specific, clinically identifiable, neurological disorder.

The Ph.D. thesis consists of three parts.

The first study was a retrospective study on medical records of 201 consecutive Danish patients suspected of suffering from all types of vulvodynia and who were referred to a vulvar outpatient clinic (Department of Gynecology, Rigshospitalet University Hospital) between October 2003 and January 2006. The aim of the study was to identify objective clinical signs of vulvodynia and to determine specific diagnostic tests for vulvodynia in women referred to a vulvar outpatient clinic for vulval complaints. On a long term basis the study was aimed at contributing to national guidelines on diagnosing and treating vulvodynia patients.

The second study was primarily set up to evaluate the effect of injection of 20 I.E. Botulinum toxin A (BTX-A) as a treatment for vulvodynia in a randomised, double blinded, placebo-controlled study. Secondary aims were to investigate the ability of BTX-A to relieve dyspareunia, improve sexual function, increase quality of life and relieve psychological distress. Sixty-four women,

diagnosed with provoked vestibulodynia (a localized form of vulvodynia) and recruited from the outpatient department for vulva diseases in the Department of Gynecology, Juliane Marie Center, Rigshospitalet University Hospital, Copenhagen between April 2005 and September 2007, were randomised and injected with BTX-A or placebo (Saline). The primary endpoints (pain and dyspareunia) were evaluated monthly and the secondary endpoints were evaluated every third month until twelve months after treatment. Study 3 furthermore assessed the degree of depression, sexual dysfunction, quality of life, personality among women referred to a vulvar outpatient clinic and whether the patients' level of sexual (dys)function, psychological distress, degree of depression and personality profile could predict the outcome in the randomised Botox study.

The results of the first study demonstrated that self-reported dyspareunia and stinging pain is strongly associated with vulvodynia. Self-reported pruritus and a tendency toward fissures are not likely to be associated with vulvodynia. The authors conclude that the question whether biopsies from the vulva should be performed regularly when redness and pain is present, must be explored further in prospective studies.

The results of the second study demonstrated that injection of 20 I.E. BTX-A in the vestibule of women diagnosed with vulvodynia does not reduce pain, improve sexual functioning, or impact the quality of life compared to placebo after six months follow up. Both the BTX-A group and the placebo groups experienced a statistical significant reduction in pain on the VAS Likert scale at 6 months follow up within the groups but not between the groups.

Study three demonstrated that among the participants in the RCT, 14 – 20 % had a mild to moderate depression. The third study further found that women with vulvodynia scored significantly higher in the Neuroticism - and Openness domains according to the NEO PI-R (five factor personality profile) than a Danish general population.

In the light of the three studies the authors conclude that an injection of 20 I.E. BTX-A in the vestibule of women diagnosed with vulvodynia is not superior to placebo (Saline) in reducing vulvar pain. BTX-A injection does not improve sexual functioning nor impact the quality of life compared to placebo. Women with vulvodynia often have difficulty with sexual function, may be depressed and psychologically as well as sexually distressed, which may need to be addressed in conjunction with pain to eliminate the disorder.

This first Ph.D. study furthermore concludes that specific complaints, objective signs found on examination in women suspected of suffering from vulvodynia and signs of psychological distress may predict a final diagnosis. The third study underlines the impairment of the psychological well being and stipulates, that the psychological characteristics needs to be assessed and included in the evaluation and treatment program for the individual patient with vulvar complaints to allocate the patient to the most appropriate treatment. Although somatization, depression, psychological distress

and potentially a certain personality profile may be a consequence of a chronic pain condition, such traits may actually precede the development of pain.

Based on the findings in the studies the author recommends that a multidisciplinary diagnostic evaluation – and treatment program seems appropriate to encounter the many aspects of the condition, in which some patients may need psychosexual treatment as first line treatment and others more physical or medical treatment.