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The Genito-Pelvic Pain/Penetration Disorder Paradigm and Beyond

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CHAPTER

3

Long-Term Results of an Individualized, Multifaceted, and Multidisciplinary Therapeutic Approach to Provoked Vestibulodynia

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ABSTRACT

Introduction. Although it is highly recommended to use a multifaceted approach to treat provoked vestibulodynia (PVD), the large majority of treatment studies on PVD used a one-dimensional approach.

Aim. To evaluate the long-term treatment outcome of a multifaceted approach to vulvar pain, sexual functioning, sexually related personal distress, and relational sexual satisfaction in women with PVD.

Methods. Retrospective questionnaire survey 3–7 years after treatment.

Main Outcome Measures. Sexual functioning, sexually related personal distress, and relational sexual satisfaction were measured using the Female Sexual Function Index (FSFI), the Female Sexual Distress Scale (FSDS), and the Dutch Relationship Questionnaire (NRV), respectively. An additional questionnaire assessed socio-demographic variables, intercourse resumption, and the level to which the women would recommend the treatment to other women with PVD. Post-treatment vulvar pain scores were obtained using a visual analog scale (VAS). Pretreatment scores were reported in retrospect on a separate VAS.

Results. The questionnaires were completed by 64 out of 70 women (91%). Mean follow-up was 5 years (range 3–7). Comparison of the mean pretreatment and post-treatment VAS scores showed a significant reduction in vulvar pain. Pain reduction was reported by 52 women (81%), whereas no change and pain increase were reported by 7 women (11%) and 5 women (8%), respectively. Post-treatment, 80% of the women had resumed intercourse. Only 5 women (8%) reported completely pain-free intercourse. Comparisons with age-related FSFI and FSDS Dutch norm data showed that scores for sexual functioning in the study group were significantly lower, while scores for sexually related personal distress were significantly higher. There were no significant differences in relational sexual satisfaction ratings between the study group and the NRV Dutch norm data.

Conclusion. These retrospective data on long-term treatment outcome support the hypothesis that a multifaceted approach to PVD can lead to substantial improvements in vulvar pain and the resumption of intercourse.

INTRODUCTION

Provoked vestibulodynia (PVD) was originally described by Skene in 1889 [1]. It is believed to be the most frequent cause of chronic, superficial burning vulvar pain at intercourse in premenopausal women [2]. PVD affects 12% of women in the general population [3] and has been estimated to affect 15% of women who visit gynaecological outpatient clinics [4]. The vulvar pain is associated with sexual, psychological, and relational distress [5].

Friedrich defined PVD as vulvar pain at attempted vaginal entry (e.g., intercourse, tampon, and finger insertion), tenderness to pressure with cotton tips within the vulvar vestibule, and vestibular erythema in various degrees [6]. However, erythema is not a strong and reliable diagnostic criterion, because its presence and severity are subject to clinical judgement [7].

Other information is usually taken into account to diagnose PVD in addition to Friedrich's criteria, e.g., the presence of symptoms for at least 3–6 consecutive months and the exclusion of other causes of acquired superficial dyspareunia [8].

The etiology of PVD is considered multifactorial, including physical factors (inflammatory reactions, infections, antigen, genetic, and hormonal influences) and psychosexual factors.

Hypertonicity of the pelvic floor muscles has also been demonstrated [9]. According to the neuro-matrix theory, pain results from activity in the neural network rather than directly from sensory input evoked by injury, inflammation, or other pathology [10]. Dysfunction of the neuronal system (neuropathic pain) should also be considered in the pathogenesis of PVD [11–16].

There is no consensus about the treatment approach to PVD. During the International Consultations on Sexual Dysfunctions in 2004, a multidimensional and multidisciplinary approach was advocated, with specific attention to six main areas: the mucous membrane, the pelvic floor, the experience of pain, sexual and relational functioning, psychosocial adjustment, and genital/sexual abuse [17].

Nevertheless, the majority of treatment studies on PVD used a one-dimensional approach. Until now, only three studies have been published on a multifaceted and multidisciplinary treatment approach. However, their follow-up period was limited (8, 30, and 6 months, respectively) [18–20].

In most of the studies on PVD, the success rate of treatment was exclusively related to the degree of persistent coital vulvar pain. Other factors that might influence overall treatment outcome, e.g., quality of sexual functioning, sexually related personal distress,

relational sexual satisfaction, awareness that painless intercourse can be achieved, and intercourse resumption, have rarely been analyzed [21]. In the present study, we evaluated the outcome of a multifaceted and multidisciplinary treatment approach, while taking into consideration multiple domains of functioning that are affected by this distressing pain problem.

AIM

The purpose of our study was to evaluate the long-term treatment outcome of an individualized, multifaceted, and multidisciplinary therapeutic approach to coital vulvar pain, sexual functioning, sexually related personal distress, and relational sexual satisfaction in women diagnosed with PVD.

METHODS

A retrospective questionnaire was administered to 64 women diagnosed with PVD who had received individualized, multifaceted, and multidisciplinary treatment (Table 1) at the University Medical Center in Groningen (UMCG) between 2002 and 2006. Based on the results of a prospective randomized and multifactorial study at the UMCG (the Netherlands) in 1996, we concluded that an individualized, multifaceted, and multidisciplinary therapeutic approach is the treatment of choice for women diagnosed with PVD [18]. An integrated approach was taken: thorough evaluation of the complaint and a tailored course of action that consisted of conservative local measures (i.e., vaginal electromyogram [EMG] biofeedback and pelvic floor physiotherapy, sex therapy, and/or psychotherapy), and in some cases - after careful deliberation with the patient and when applicable also the partner - surgical intervention [22,23]. This approach was conducted by a multidisciplinary team consisting of a coordinating gynecologist/ sexologist, registered pelvic floor physiotherapists, and registered psychologists and sexologists. All the women received steps 1–9 and if appropriate, step 10, 11, or 12. Therefore, psychotherapy and surgery did indeed form part of the multifaceted approach. At the time of treatment, the women were either sexually active without penetration or sexually abstinent. At the first visit, all the women were seen by a gynecologist/sexologist (W.W.S) at the gynecological department of the UMCG. After an educative gynecosexological examination and, if appropriate, cultures, vulvoscopy, and dermatological consultation (to exclude other causes of superficial vulvar pain), the diagnosis was confirmed. To take part in the present study, women were required to meet the following inclusion

criteria: (i) self-reported, superficial vulvar pain at attempted vaginal entry (e.g., intercourse, tampon- and finger insertion); (ii) tenderness of the vestibular area even upon light touching with a cotton tip; (iii) presence of symptoms for at least 6 consecutive months; and (iv) exclusion of all other causes of acquired superficial dyspareunia (including vaginismus). Although erythema is usually present, it was not an inclusion criterion. In February 2009, women who met our inclusion criteria were invited by phone to participate in this study by an independent researcher. Participants gave informed consent.

Between March 2009 and April 2009, a letter of introduction and a battery of questionnaires (visual analog scale [VAS], Female Sexual Function Index [FSFI], Female Sexual Distress Scale [FSDS], and Dutch Relationship Questionnaire [NRV]) were sent to the participants to obtain data on the long-term post-treatment situation.

Upon receipt the completed questionnaires, all relevant patient data were retrieved and transferred into an anonymous, password-protected, database. The identity of the participants was protected by study-specific, unique patient codes; true identity was only known to one dedicated data manager. According to Dutch regulations, these precautions meant that no further institutional review board approval was needed (<http://www.federa.org/>).

VAS

To obtain pretreatment coital vulvar pain measurements, the women were asked to indicate their score in retrospect on a horizontal VAS. Post-treatment outcome scores were reported on a separate VAS. The VAS is widely recognized as a quantitative index of pain [24,25]. It consisted of a 10-cm line anchored at the end points with the words "no pain" at 0 and "worst possible pain ever experienced" at 10.

FSFI

The participants filled in the FSFI to obtain long-term outcome data. It is a brief, self-report measure of female sexual function composed of six subscales: desire, arousal, lubrication, orgasm, satisfaction, and pain. Total FSFI score can range from 2 to 36. Lower scores indicate poorer sexual functioning. A Dutch language version of the FSFI was used. The internal consistency of the FSFI within our sample was high (Chronbach's alpha = 0.96). In accordance with Ter Kuile et al. we report the total score, because the discriminative value of the total FSFI score is on par with the combined use of the six subscales. For comparison purposes, norm values were used that were obtained from

108 Dutch women without sexual problems during validation of the Dutch version. Mean age of the comparison population was 27.1 years (SD 9.4) [26–28].

Table 1. The multifaceted and multidisciplinary therapeutic approach

1.	Careful history taking
2.	An educative gynecological examination that the patient was able to follow with a hand mirror (and when applicable with the partner present)
3.	Providing information about provoked vestibulodynia (PVD), its natural course, treatment options, and a treatment plan
4.	Involvement of the patient and partner in the decision process about potential treatment options
5.	Prescription of an inert cream (simple eye ointment) to protect the vestibular area and to urge the woman to touch the painful area (mucosal desensitization)
6.	Vaginal EMG biofeedback, pelvic floor physiotherapy (<i>by a registered pelvic floor physiotherapist</i>) with the aim of alleviating pelvic floor hypertonia
7.	Homework assignments that comprised self-exploration of the genitals and biofeedback by means of digital control, or with the aid of vaginal dilators and lubricants, together with a temporary coitus prohibition
8.	A hygienic protocol, e.g., no vaginal douching, no press-on panty liners
9.	Normalizing, reframing, and encouraging sexual activity without penetration to avoid development of feelings of guilt
10.	If appropriate, individual sexual counseling that aimed to improve the woman's self-image, body-image, and autonomy, with the aid of a registered <i>psychologist/sexologist</i>
11.	If appropriate, sexual partner-relation therapy that primarily aimed to improve physical and noncoital sexual contact, with the aid of a <i>registered psychologist/sexologist</i>
12.	If appropriate in some cases of persistent PVD, surgical intervention (vestibulectomy) as an additional form of treatment to facilitate breaking the vicious circle of irritation, pelvic floor muscle hypertonia, and sexual maladaptive behavior [18]. Surgery was performed by a gynecologist/sexologist (W.W.S).

FSDS

The participants filled in the FSDS in relation to their experience over the previous 30 days to assess sexually related personal distress in the long-term. The FSDS consists of 12 items about negative feelings and problems that were bothersome or had caused distress during the past 30 days. Total FSDS score can range from 0 to 48. Higher scores indicate greater sexual distress. A Dutch language version of the FSDS was used. The internal consistency of the FSDS full scale score within our sample was high (Cronbach's alpha = 0.96). For comparison purposes, norm values were used that were obtained from 108 Dutch women without sexual problems during validation of the Dutch version [29].

NRV

NRV was used to obtain data on various aspects of the women's intimate relationship. It consists of 80 items, divided into five subscales: independence, emotional solidarity, identity, conflict handling, and sexuality. The total NRV score provides a general impression of the quality of the relationship. In this study, we only report the total score on the scale "sexuality" (SE). Low scores indicate lower sexual satisfaction and poorer sexual compatibility. The internal consistency of the NRV within our sample was high (Cronbach's alpha = 0.82). For comparison purposes, we used a specific norm group of 2,059 women without dyspareunia, whose mean age was 45.3 years (SD 12.9) [30].

STATISTICAL ANALYSIS

Data were analyzed using the statistical analysis program SPSS, version 16.0 (SPSS Inc., Chicago, IL, USA). To test for significant differences in vulvar pain between the pretreatment VAS score and the post-treatment VAS score, paired *T*-tests were used. Significant differences in the FSFI, FSDS, and NRV scores between our participants and the (age-related) norms from the comparison groups were tested by calculating 95% confidence intervals.

RESULTS

PATIENT CHARACTERISTICS

A total of 70 women met our inclusion criteria. An independent researcher approached them by telephone and 64 (91%) agreed to participate and gave informed consent. Four women dropped out because they found the questions too intimate and two more dropped-out due to lack of motivation. Mean follow-up was 5 years (range 3–7). Characteristics of the women (N = 64) at the time of our questionnaire survey are shown in Table 2. There were no significant correlations between the socio-demographic characteristics of the participants and the outcome variables. All of the women (N = 64) had received treatment steps 1–9 (as shown in Table 1.), while 27 women (42%) had also received psychotherapy and 15 women (23%) had undergone surgery. Mean duration of treatment was 148 weeks.

Table 2. Characteristics of the study population at the time of the questionnaire survey

Data	Study population (N=64) Mean (range) or N		%
Age (yrs)	29.3 (20-39)		---
Duration of symptoms (years)			
< 2	9	14	
3-5	30	47	
6-10	15	23	
> 10	10	16	
Vestibulodynia			
Primary	38	59	
Secondary	26	41	
Civil state			
Married	23	36	
Single	8	13	
Living together	29	45	
Relationship, but not living together	4	6	
Highest education			
University	12	18	
Higher education	24	38	
Secondary education	28	44	
Sexual abuse			
Yes	16	25	
No	48	75	
Tricyclic antidepressants			
Yes	3	5	
No	54	84	
Other medication	7	11	
Use of oral contraceptive			
Yes	26	41	
No	27	42	
Other contraceptive	11	17	
Nulliparous			
Yes	21	33	
No	43	67	

COITAL VULVAR PAIN

Table 3 shows the VAS vulvar pain scores pretreatment and post-treatment, and also the vulvar pain reduction after treatment. Paired *T*-tests revealed significant reductions in pain ($P < 0.001$).

Vulvar pain reduction following individualized, multifaceted treatment was reported by 81% (N = 52) of the women; 11% (N = 7) reported no change, and 8% (N = 5) reported

increase in pain. Post-treatment, 80% of the women had resumed intercourse. Only five women reported completely pain-free intercourse.

Table 3. Visual analog scale vulvar pain scores pretreatment, post-treatment, and vulvar pain reduction after treatment (mean score and SD)

	Patient population (N=64)
Vulvar pain pre-treatment	7.4 (SD 1.4)
Vulvar pain post-treatment	3.8 (SD 2.8)
Vulvar pain reduction	3.6 (SD 2.9)*

*P < 0.001

SEXUAL FUNCTIONING, SEXUALLY RELATED PERSONAL DISTRESS, AND RELATIONAL SEXUAL SATISFACTION

Table 4 shows the FSFI, FSIDS, and NRV-SE scores post-treatment. Quality of sexual functioning on the FSFI was significantly lower than the norm in the age-related Dutch comparison group, while sexually related personal distress on the FSIDS was significantly higher. There were no significant differences in relational sexual satisfaction between the study population and the norm in the Dutch NRV comparison group.

Table 4. Sexual functioning (FSFI), sexually related personal distress (FSIDS) and relational sexual satisfaction (NRV-SE) in the study population and comparison groups (mean score and SD)

	Study population (N=64)	Comparison group(s)
FSFI	19.7 (SD 3.5) 18.5-20.1*	31.2 (SD 3.9) (N=108)
FSIDS	18.6 (SD 13.2) 14.5-21.0*	5.1 (SD 6.4) (N=108)
NRV-SE	8.0 (SD 2.7) 7.4-8.8*	7.8 (SD 3.2) (N=2,059)

*95% confidence interval.

FSFI = Female Sexual Function Index; FSIDS = Female Sexual Distress Scale; NRV-SE = Dutch Relationship Questionnaire-Sexuality.

RECOMMENDATION OF THE TREATMENT TO OTHER WOMEN WITH PVD

A high percentage (80%) of the women reported that they would recommend similar multifaceted and multidisciplinary treatment to other women with PVD.

DISCUSSION

Since 1996, a multifaceted therapeutic approach has been recommended for the treatment of PVD [17,18,22]. However, the majority of treatment studies on PVD used a one-dimensional approach [17,18,22,31–37]. Although a one-dimensional approach is preferable to assess the therapeutic outcome of one specific intervention, its singularity will also undoubtedly affect the ultimate results. These one-dimensional studies, with pain reduction during intercourse as the most important outcome criterion, demonstrated that vaginal EMG biofeedback combined with pelvic floor physiotherapy, cognitive behavioral therapy, and vestibulectomy are useful interventions. Success rates were 50–70%, 40–50%, and 61–93%, respectively [17]. An explanation for the high success rates of vestibulectomy is that women might consider the radical removal of painful structures as the maximum acknowledgement of their PVD. However, in the literature, 9% of vestibulectomy participants reported increased pain at long-term follow-up [22].

In this study, we evaluated the long-term treatment outcome of an individualized, multifaceted, and multidisciplinary therapeutic approach. Significant vulvar pain reduction was observed between pretreatment and post-treatment in 52 women (81%). However, seven women (11%) reported no change and five women (8%) reported an increase in vulvar pain. Post-treatment, 80% of the women had resumed intercourse, but only five women reported completely pain-free intercourse. Thus, even after a “successful” therapy outcome (81% pain reduction), intercourse remained a hypersensitive act in the majority of these women [19]. This was also reflected in our findings that the quality of sexual functioning was significantly lower than the FSFI norm, while sexually related personal distress was significantly higher than the FSDS norm. However, we did not find any significant differences in relational sexual satisfaction between the study population and the NRV comparison group, which might mean that these women were able to adapt to the circumstances, despite the persistence of vestibular pain.

Many women with PVD stress that their partner becomes angry and frustrated at the infrequency and low quality of their sex life. This results in loss of excitement and intimacy for both partners [38]. Avoidance reactions are common, and may obstruct the sexual rehabilitation [39]. In our opinion, strengthening of the intimacy aspects of the sexual relationship continues to be a crucial element in the recovery process of women with PVD.

Ultimately, the couple will need to renegotiate their sexuality and intimacy after the diagnosis of PVD, in the same way gynecological cancer patients do [40,41]. Thus, they need to find a way to continue their sexual relationship, despite the presence of symptoms.

There is evidence that psycho-educational interventions can improve sexual functioning under these circumstances [35]. Although we did not measure this impact, we believe that our multifaceted treatment offers all the ingredients to achieve improvement from this angle. It was striking, for example, that 80% of our participants would recommend the multifaceted approach to other women with PVD.

PVD probably encompasses mechanisms of neurogenic inflammation as well as neuropathic pain (as is also the case in other related pain conditions). Such a combination may lead to the development of sexual pain disorders, with less efficient pain modulating processing [17]. At present, we do not have the tools to completely correct disturbances in pain modulating processes. Thus, the pain may persist to a greater or lesser extent, despite the removal of all the factors related to the development, maintenance, or exacerbation of PVD symptomatology.

This might explain the persistence of low scores on sexual functioning after treatment. In our opinion, it is important that women with PVD should be fully informed about this inability prior to starting treatment.

Until now, only three studies have been published on the multifaceted therapeutic approach to PVD [18–20]. Schover et al. employed structural collaboration between a gynecologist and a psychologist to evaluate and treat 32 women with PVD. Their comprehensive treatment approach comprised local excision of vulvar lesions and consultations with the psychologist, including Kegel exercises, vaginal dilation, and couple therapy [19]. After a mean follow-up of 8 months, the success rate was 40–60%. This somewhat disappointing result might have been caused by the short duration for the psycho-sexual intervention, which, on average, was only two or three consultations. Weijmar Schultz et al. treated 48 women with PVD in the first phase of their study using behavioral therapy (with or without preceding surgery). In the second non-randomized part of the study, the women and their partners were given the choice of whether or not to include surgery. The nonsurgical approach was chosen first by 82% of the women. At 2 to 3 years after treatment, 79–89% of the women reported positive effects from the intervention: their complaints had disappeared, diminished, or (although unchanged) were considered to be less of a problem. The differences in outcome between the treatment groups were not statistically significant [18].

Backman et al. offered standardized physiotherapy and psychosexual therapy to 24 patients with PVD. A midwife supervised exercises for mucosal desensitization and reestablishment of the pelvic floor muscle function. Follow-up measurements were performed after 6 months.

The mean number of appointments with the psycho-sexual counsellor was 12 (range 4–24), while the mean number with the midwife was 12 (range 9–26). Surgery was not an option. In the group of 24 women, 19 (79%) considered themselves to be cured or greatly improved [20].

In our study the mean duration of individualized, multifaceted and multidisciplinary treatment was 148 weeks, which was considerably longer than other studies. This may have been due to our specific population of patients, who were referred from all over the Netherlands due to "therapy-resistance".

The present study has a number of shortcomings. It was retrospective; there was a lack of pre-treatment measures in the questionnaires; and there was no control group. Therefore, the outcome of the study should be interpreted as purely "preliminary." Nevertheless, the results make a significant contribution, given the scarcity of existing research into the multifaceted treatment approach. In addition, the positive effects of an individualized, multifaceted, and multidisciplinary approach to PVD are emphasized and in comparison with other studies, the duration of follow-up was longer.

The study clearly demonstrates that PVD goes far beyond the experience of pain. Long-term, randomized, multifaceted, and prospective studies are needed and should not be restricted exclusively to pain reduction, but should also include other factors that influence treatment outcome, e.g., the quality of sexual functioning, sexually related personal distress, relational sexual satisfaction, awareness that painless intercourse can be achieved, and intercourse resumption.

CONCLUSIONS

Our individualized, multifaceted, and multidisciplinary treatment approach to PVD led to vulvar pain reduction in the long-term in more than 80% of the women. We also found that 80% had resumed intercourse and 80% would recommend a similar multifaceted therapeutic approach to other women with PVD. Although these data were gathered in retrospect, they support the hypothesis that an individualized, multifaceted, and multidisciplinary therapeutic approach can have positive long-term effects. However, even after what can be considered as "successful" therapy outcomes, intercourse remained a hypersensitive act in the majority of women. Therefore reinforcement of

the intimacy aspects within the sexual relationship may constitute a major theme in the treatment of PVD.

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