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Title

COMPARISON OF MOTOR FUNCTION AND PERCEPTION OF HEALTH BETWEEN WOMEN WITH PROVOKED VESTIBULODYNIA AND HEALTHY CONTROLS

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ABSTRACT

Background: Provoked vestibulodynia (PVD) is a prevalent and disabling condition in women and may be associated with reduced quality of life and impairment of physical functioning.

Aim: to investigate whether women with PVD have different motor functions, posture and breathing patterns to asymptomatic controls. Furthermore to study whether they perceive their physical health differently.

Outcome: The Standardized Mensendieck Test (SMT) and The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) were used to assess differences between 35 women with PVD and 35 healthy controls.

Results: There were no statistically significant differences in any of the five motor domains of the SMT in women with compared to without PVD; standing posture (4.0 (SD 0.6) vs 5.0 (SD 0.6)), gait (4.7 (SD 0.6) vs 4.8 (SD 0,6)), movement (4.8 (SD 0.8) vs 5.1 (SD 0.6)), sitting posture (4.7 (SD 1.0) vs 4.9 (SD 0.8)) and respiration (4.7 (SD 1.0) vs 4.7 (SD 0.9). Women with PVD scored significantly lower on all scores on SF-36 (adjusted Bonferroni p=0.002) except for physical functioning.

Clinical implications: As no difference in SF-36 physical functioning nor the five domains of the SMT was found between women with and without PVD, the value of interventions focusing on general physical function is un-clear.

Strengths and limitations: The strength of the present study was the use of an assessor-blinded case-control design, trained physiotherapists to conduct the tests and use of valid and reliable outcome measures. A limitation was the homogeneity of the sample including young nulliparous women and therefore the lack of ability to generalize to other study populations.

Conclusion: Young nulliparous women with PVD did not score differently from a group of healthy controls on assessment of overall physical functioning, nor standing posture, gait, movement, sitting posture and respiration. However, their score on perception of general health was lower in women with PVD compared to the control group.

Key words: The Standardized Mensendieck Test (SMT), 36-Item Short-Form Health Survey (SF-36), Provoked Vestibulodynia, breathing, motor control, movement, physiotherapy, posture.

INTRODUCTION

Vulvodynia is defined as “Vulvar pain of at least 3 months' duration, without clear identifiable cause, which may have potential associated factors.” [1]. The etiology of PVD is postulated to be multifactorial, with inflammatory, hormonal, congenital, genetic, neuroproliferative and muscular factors as contributing factors [2]. These muscular factors are considered to be specifically related to the pelvic floor muscles [2;3]. Vulvodynia may be described as localized or/and generalized, provoked or spontaneous, primary or secondary and also present with a varying temporal pattern (intermittent, persistent, constant, immediate, delayed) [1]. Provoked vestibulodynia (PVD) has been recognized as the leading cause of premenopausal chronic vulvar pain. [4]. A Swedish population study found a prevalence of 13% of vulvodynia for women aged 20-29 [5]. The impact of PVD is significant [6]. PVD causes pain with penetration in the majority of women and may contribute to fear of pain [7], and severely affect sexual relationship and quality of life [6] .

Physiotherapy, including pelvic floor muscle therapies is recommended in most guidelines for treatment of vulvodynia [8;9]. However these recommendations are informed mostly by observational studies. A more recent systematic review has found physical therapy modalities – mostly combinations of several behavioral, exercise and manual therapies directed to the pelvic floor muscles – were effective for decreasing pain during intercourse and improving sexual function [10]. The therapy focus to date has been on pelvic floor muscle relaxation, due to an observed association with increased pelvic floor muscle tone and PVD in some studies [11-14], however not all studies have observed this [15].Some studies have utilized both active PFM contraction as well as active PFM relaxation to achieve reduction in tone [16-18]. Despite the rationale for therapy to target the pelvic floor muscles, several studies have included interventions to improve global muscle relaxation and breathing techniques together [19;20]. The rationale for a more general approach to therapy could be that for most sufferers, PVD is a chronic pain condition, and that central and peripheral factors should be considered. Guidelines recommend clinical care for vulvodynia should follow the principles of general chronic pain management, and that treatment should be holistic and focus not only on the primary site of pain but on its subsequent impact on the patients’ lifestyle and sexual functioning [8] . However

studies which have provided multimodal therapies did not assess general muscle relaxation, posture and respiration in participants before and after treatment, therefore no conclusions can be drawn of the effectiveness of these interventions in women with PVD.

In a case-control study, Haugstad et al [21] found that women with chronic pelvic pain had a specific pattern of posture, movement, muscle pathology, and reduced body awareness compared to healthy controls using the Standardized Mensendieck Test (SMT). The SMT is based upon observation and analysis of respiration, posture and motor function, and was developed to evaluate patients with psychosomatic disorders. It has been found to reliable and valid assessing patients with chronic pelvic pain [22] . Following the case-control study results, Haugstad et al [23]conducted a randomized controlled trial (RCT) in women with non-specific chronic pelvic pain, applying a combination of Mensendieck exercises and cognitive therapy, named Mensendieck Somatocognitive Therapy. Participants with chronic pelvic pain significantly improved scores for all motor function and respiration patterns, and reduced pain by 50% compared with the control group [23]. Further improvement was seen 9 months after cessation of treatment [24] . As PVD is a pelvic pain condition, it might be postulated that patients with PVD may have the same change in posture, movement patterns and respiration. This was tested in a recent study by Haugstad et al [25] young women with PVD were found to have a better score in all domains on the SMT test than women with chronic pelvic pain, but worse than historical controls. However, both groups of participants were drawn from different populations, were not assessed contemporaneously and, hence, the assessors were not blinded to the background of the participants.

To date, there is scant knowledge whether there are any difference between women with and without PVD in impairments of posture, global muscle function, breathing patterns and self-report of general health. Therefore, the purpose of the present study was to evaluate if women with PVD have different posture, function of movement and breathing patterns than asymptomatic controls and furthermore if they perceive their general health differently.

METHODS

This is an exploratory, secondary analysis of an assessor-blinded comparison study. The primary aim of the initial study was to compare PFM variables, measured with manometry (vaginal resting pressure, PFM strength and PFM endurance) and sEMG between women with PVD and controls, and the results have been reported elsewhere [15]. The secondary aim presented here was to investigate if the two groups differed in global physical function and perception of health. The measurement tools used were the SMT and SF-36.

Study approval was obtained from the regional Committee for Medical and Health Ethics South-East (REK South-East D) (2010/3257-1). All subjects gave written informed consent before entering the study.

Participants

Gynecologists at the Oslo University Hospital and in private practice in the Oslo region recruited women aged 16-38 years diagnosed with PVD for the study. Control participants were recruited through friends of the women with PVD and via the internet, public advertisements and work colleagues. The participants were diagnosed by gynecologists according to current vulvodynia guidelines, and a blinded cotton swab test confirmed the diagnosis [15]. Inclusion criteria for the study were nulliparity and ability to understand Scandinavian languages. Exclusion criteria were presence of candida and inability to contract the PFM correctly. The latter was assessed by observation of inward movement of the perineum by an experienced women's health physiotherapist.

Power calculation

As this study was a secondary analysis, a power calculation was not performed for this study. A power calculation was done for the primary outcome of the primary study [15]. When planning the primary study, no vaginal pressure data from patients with PVD were available. We therefore used the difference in PFM strength between women with and without urinary incontinence: 6.6 cm H2O (CI 2.3–10.8) reported in Hilde et al [26]. With a two-tailed test, significance level <0.05, and power 80%, at least 35 participants were required in each group of the primary study. Data from the same 70 participants are reported in this study.

A comprehensive questionnaire, undertaken at the Vulvaclinic in Oslo University Hospital, was modified for the purpose of this study. Socio-demographic data and medical history were collected including self-reported measures, such as onset and duration of symptoms, frequency of yeast infections, urinary and bowel symptoms, use of contraceptives and physical activity habits.

Outcomes

Primary outcome: Standardized Mensendieck Test (SMT)

The SMT evaluates five motor domains; standing posture, gait, movement, sitting posture and respiration. It consists of 23 test items, each given a score on a scale from 0-7, with 7 representing optimal function. Thescore of each subtest and motor domain can be used independently [22]. The full test protocol takes 5-7 minutes. The test has been found to have intraclass correlation coefficient (ICC) scores from 0.82 to 0.97 in the hands of experienced Mensendieck physiotherapists and it discriminates well between women with chronic pelvic pain – as classified by the International Statistical Classification of Diseases and Related

Health Problems (ICD 10) – and matched healthy controls (sensitivity 0.9, specificity 0.7) [22].

Secondary outcome: SF-36

The Medical Outcomes Study 36-Item Short-Form Health Survey (SF-36) [27], the 8 item reliable and validated version translated into Norwegian [28], was used to report perceived general health. Each item represents one dimension of the SF-36. Items include: general health (GH), which refers to personal evaluation of health, including current health, health outlook and resistance to illness; physical functioning (PF), which refers to the extent to which health limits physical activities such as self-care, walking, climbing stairs, bending, lifting and moderate and vigorous exercises; role/physical (role of physical health problems in work or other daily activities) (RP), which refers to the extent to which physical health interferes with work or other daily activities, including accomplishing less than wanted, limitations in the kind of activities, or difficulty in performing activities; bodily pain (BP), which refers to the intensity of pain and effect of pain on normal work, both inside and outside the home; vitality (VT), which refers to feeling energetic and full of 'pep' versus feeling tired and worn out; social functioning (SF), which refers to the extent to which physical health or emotional problems interfere with normal social activities; mental health (MH), which refers to general mental health, including depression, anxiety, behavioral-emotional control, general positive affect; and role/ functioning emotional (RE), which refers to the extent to which emotional problems interfere with work or other daily activities, including decreased time spent on activities, accomplishing less and not working as careful as usual [29]. Using the Research and Development Corporation (RAND) scoring system, scores in each domain range from 0 to 100, with higher scores indicating better functioning. Scores above and below 50 are considered above and below the average in the general US

population [20]. The SF-36 is recommended to be used in vulvodynia clinical trials as a self-report outcome measure [30].

Procedure

The participants were informed by one physiotherapist (IN) about the questionnaires and the purpose of blinding of another Mensendieck physiotherapist performing the SMT. All patients was requested not to converse except when asked to, as the examiner was following a strict protocol [22]. All tests were done in the same room and by two experienced Mensendieck physiotherapists blinded to patient group affiliation.

Statistical analyses:

Background variables are presented as means with standard deviation (SD) or numbers with percentages (%). Student T-test was used to analyze differences between groups. Significance level was set to ≤ 0.05. Bonferroni correction for multiple comparisons gave a p-value of ≤ 0.01 for SF-36, ≤ 0.002 for all 23 subscores on SMT and ≤ 0.01 for the 5 average scores of each domains of the SMT.

RESULTS

Table 1 shows the background variables of the study group. Mean age of the participants was 24.3 years (SD 4.7) and mean BMI 22.0 kg/m^2 (SD 2.6). Most women in both groups reported being physically active at least once a week, and approximately 20% of both samples were

performing PFM exercises. There were no significant differences between women with and without PVD in any background variables.

Using Bonferroni to correct for the effect of multiple testing, Table 2 shows no statistically significant differences between groups in any items of the SMT. The results show that women with PVD had a lower score on knee stability (P=0.04) and a tendency to reduced ability compared with controls to move their arms in a free pattern (P=0.05).

Table 3 shows the results of the SF-36 and comparison between women with and without PVD. Women with PVD had statistically significant lower scores on all variables, except for physical functioning (PF). Bonferroni correction revealed significant differences on 6 out of 8 variables; non-significant difference are seen in the variables of physical functioning (PF) and Role Emotional (RE).

DISCUSSION

The results of the present study found that that young, nulliparous women with PVD were not different from controls in any motor function variables, including posture and respiration, as assessed by the SMT. However, women with PVD scored significantly lower on all items (Role Physical, Bodily Pain, General Health, Vitality, Social Functioning, Role Emotional and Mental Health) of the SF-36 short form except physical functioning (P=0.08).

The finding that there was no difference in physical functioning between the groups assessed by the SF-36, corresponds with the results of the SMT. In the present study, women with diagnosed PVD perceived their health-related quality of life health lower than controls in all SF-36 domains, other than physical functioning and emotional role. Therefore we may conclude that women with PVD perceived their physical function and emotional role to be adequate. Our SF-36 findings are in line with other studies reporting that women with PVD have reduced quality of life and high levels of psychological stress [2;6;31;32]. However, perhaps these domains do not impact on their physical function. The interpretation of minimal impact on physical function aligns with results of another study in which women with PVD displayed only mild levels of kinesophobia [25]. The results of the SF-36 point to the impact that these women feel PVD has had on their lives, suggesting that some women may need psychological support to help them with pain-coping strategies and to learn techniques to control fear of pain [33]. A multidisciplinary approach with tailored treatment to this patient group is therefore warranted.

Our results indicate that young nulliparous women diagnosed with PVD do not differ on respiration, posture and ability to discriminate and control different body parts compared with healthy controls. This is in contrast to the recent results of Haugstad et al [25] who reported that women with PVD had reduced quality of movement, especially for gait and respiration patterns which were 50% lower than optimal scores. However, in contrast to our study which included a real-time matched control group, their comparison was based on data from 15 control women obtained 10 years earlier. Historical controls can be different in both background variables of the population studied, societal factors and outcome measures and such results must therefore be interpreted with caution.

Based on their findings, Haugstad et al [25] suggested that physiotherapy for women with PVD should focus to a lesser degree on specific anatomic structures, and more on "general body awareness, ability to relax, improved ability to cope with negative emotions and thoughts, and structure exposure to pain associated activities". Our results indicate that women with PVD do not demonstrate impaired physical function, which suggests that treatment strategies aiming to improve general physical function may not improve the patient's experience of PVD.

Previous studies which investigated the effect of a global treatment approach to vulvodynia included progressive muscle relaxation and abdominal breathing [14] , muscle control exercises [31], deep breathing, global body relaxation, stretching of hip muscles [19], joint mobilization [32], myofascial release, muscle energy techniques and stabilizing exercise [34] and global relaxation technique such as yoga and "auto-training" [35]. However, some of these studies are case reports with low internal and external validity. In addition, a

prerequisite for applying these global techniques would be that the patients score adversely on these functions measured by responsive, reliable and valid instruments/tools, such as the SMT [22] . Our findings suggest that young women with PVD do not demonstrate such impairments, and we therefore question the value of interventions with the sole or preferential aim of improving general physical functioning in women with PVD, where no limitations in these domains exist. Non-evidence based practices should be questioned [36], and we must be mindful of the treatment burden to vulnerable patients [37] of undertaking therapies that may not address their primary impairments. However, our present study was not a RCT, and we agree with Morin et al [10] that there is a need for robust and well-designed randomized controlled trials to determine the effect of different physiotherapy modalities in women with PVD.

Strengths of the present study are inclusion of women with PVD diagnosed using recommended international methods [8;38], contemporaneous comparison with age-matched controls, blinding of assessors, use of reliable and valid outcome measures and assessment by experienced physiotherapists. A limitation is that the power calculation was based on assessment of pelvic floor muscle strength, and an a-priori power calculation was not conducted for the SMT or SF-36 [15]. Due to multiple testing we did a Bonferroni calculation for the comparisons of different variables. However, all original p-values are reported in Tables 2 and 3 and show that there were some trends and borderline significant findings, with women with PVD scoring lower than the control group. This may be explained by multiple testing, but lack of statistical significance may also be due to an inadequate sample size. All participants in the present study were able to correctly contract the PFM, as such, the results cannot be generalized to patients with no awareness of the pelvic floor or an inability to contract the PFM.

Haugstad et al [22;25] defined the cut-off scores for best possible discrimination between healthy controls and chronic pelvic pain patients to 4.5 on all SMT domains; they found the largest difference in scores in the domain of gait ((patients 2.70 (SD 0.11), versus controls 5.60 (SD 0.09)) and in the domain of respiration ((patients 2.88 (SD 0.14), versus controls, 5.63 (SD 0.10)) scale 0-7. [22] In our study only two of 28 items of the SMT had a score at or above 4.5, (rotation in the gait domain for both groups, and sagittal diagonal arm swing in the movement domain for the PVD group), thus we question a cut-off value to indicate normal versus below normal performance. As we have not been able to find other studies comparing SF-36 and SMT in women with PVD, our results can only be compared with a study finding that 60 chronic pelvic pain patients had significantly lower scores on SMT than 15 healthy controls [24]. However, the chronic pelvic pain patients were different in age and parity compared to the present study and a direct comparison between the studies is therefore not possible. In addition, Haugstad et al did not control for multiple testing of findings. There is a need for more blinded case-control studies comparing physical function in women with and without PVD.

As there are several knowledge gaps remaining in our understanding of PVD and its relationship with both general physical function and PFM function, future studies could address some of these by considering which women may be at highest risk of general physical and / or PFM dysfunction. These may include women with known co-morbidities of high incidence, such as past history of vaginal or urinary tract infections. Our study did not collect detailed histories related to these co-morbidities; future research may find assessment of past history of infections, and / or other known etiological factors useful in furthering our understanding of PVD.

Conclusion: Women with PVD report their health as poorer than healthy controls, except in physical functioning. They did not differ from healthy controls in ability to discriminate and control parts of the body, gait, respiration pattern, body posture in standing and sitting position or performance of different motor skills assessed by SMT. Hence, we suggest that these variables need to be assessed and found to be of clinical relevance in women with PVD before they are included in intervention programs for this group of patients.

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