Næss, I., Bø, K. (2015). Pelvic floor muscle function in women with provoked vestibulodynia and asymptomatic controls. *International Urogynecology Journal, 26*, 1467-1473.

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# PELVIC FLOOR MUSCLE FUNCTION IN WOMEN WITH PROVOKED VESTIBULODYNIA AND ASYMPTOMATIC CONTROLS

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The authors report no conflict of interest.

I Næss: Protocol/project development, Data collection/management, Data analysis, Manuscript writing/editing

K Bø: Protocol/project development, Manuscript writing/editing

Word count: abstract 229, article 3121

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The findings were presented as an oral poster at the International Urogynecological Association (IUGA) 38th annual meeting May 28 – June 1st, 2013 Dublin, Ireland

The study was supported by The Norwegian Fund for Post-Graduate Training in Physiotherapy

Condensation:

Young, nulliparous women with provoked vestibulodynia had higher vaginal resting pressure, but not higher vaginal surface EMG activity, pelvic floor muscle strength or endurance, than controls.

Short version of title:

Pelvic floor muscles function and provoked vestibulodynia

ABSTRACT

Objective: The purpose of the present study was to assess vaginal resting pressure (VRP), pelvic floor muscle (PFM) strength and endurance and surface EMG activity in women with and without provoked vestibulodynia (PVD).

Study Design: Assessor masked comparison study including 70 women. Exclusion criteria were any previous pregnancy and present candida. Sensitivity of the vulvar vestibule was rated at 3 sites with q-tip pressure measurement and a numerical rating scale for pain. VRP, PFM strength and endurance were measured with a high precision pressure transducer connected to a vaginal balloon. Pelvic floor muscle activity was measured with surface EMG. Independent sample T-test was used to analyze differences between groups. P-value was set to <0.05

Results: Mean age of the participants was 24.3 years (SD 4.7) and mean BMI was 22.0 $kg/m^2$ (SD 2.6). Q-tip pressure measurement was significantly lower and pain more severe in the PVD group at all sites of the vulvar vestibule. The PVD group had significantly higher VRP: 20.6 $cmH_2O$ (SD 7.1) versus controls: 17.3 $cmH_2O$ (SD 4.4), p=0.02. The PVD group had significantly lower muscle activity during a 10 second holding period; PVD: 465.2µV (SD 218.4), controls: 591.1 µV (SD 277.7) p=0.04.

Conclusion: Young, nulliparous women with PVD had significantly higher VRP, but this finding was not confirmed by vaginal surface EMG.

Key words: muscle activity, muscle endurance, pelvic floor muscle, provoked vestibulodynia, resting pressure

## INTRODUCTION

The International Society for the Study of Pain have classified vulvodynia under the term vulvar pain syndrome [1]. According to Moyal-Barracco and Lynch [1] provoked vestibulodynia (PVD) is a subgroup of vulvodynia, and is defined as "vulvar discomfort, most often described as burning pain, occurring in the absence of relevant visible findings or a specific, clinically identifiable, neurologic disorder". Prevalence rates of vulvodynia vary between 12–16% among women attending gynecological practices, while prevalence of dyspareunia has been found to be between 10–28% in the general female population [2;3].

The major symptom of PVD is dyspareunia, and it is reported to have a negative impact on sexual function because of pain, fear of pain and reduced quality of life. Today there are no standardized treatment options [1;4]. The most important diagnostic tools are patient history, the cotton swab test (q-tip test) and inspection of the introitus [5]. The validity of the cotton swab test is questioned as long as the pressure of the q-tip used against the skin is not standardized and quantified [6].

It has been claimed that overactivity of the pelvic floor muscles (PFM) is associated with bladder pain, defecation disorders and chronic pelvic pain [7]. More specifically vaginal overactivity, lack of pelvic floor muscle strength and "restriction of the vaginal opening" have been hypothesized to be associated with PVD [8;9], but there are few studies assessing these variables in women with PVD compared to controls [10], and the reported findings on overactivity of the PFM are contradictory [9-12]. The reliability and validity of digital palpation of the PFM has been questioned [13], and vaginal surface EMG (sEMG) recordings may be flawed by cross-talk activity from other muscles. Likewise vaginal pressure measurements of strength and endurance are difficult to conduct and need the use of visual

observation of inward movement to be valid [14;15]. None of the above-cited studies used masked investigators, which may have biased the results.

We hypothesized that vaginal resting pressure (VRP) and resting surface EMG would be higher and PFM strength and endurance lower in women with PVD compared to healthy controls. The purpose of the present study was to compare VRP, PFM strength and endurance and sEMG activity during rest, maximal PFM contraction and attempts at holding between women with PVD and asymptomatic controls.

## MATERIAL AND METHODS

This was an assessor masked comparison study, 35 cases diagnosed with PVD were compared to a group of 35 healthy controls [16]. The applied terminology follows recommendations from the International Continence Society Clinical Assessment Group, except where specifically noted [17]. 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.

Participants: Gynecologists at the Oslo University Hospital and in private practice recruited women between 18–38 years of age for the study. Controls were recruited through friends of women with PVD and via the internet, advertising and colleagues at the university.

Inclusion criteria were being nulliparous diagnosed with PVD according to the International Society for the Study of Vulvovaginal Disease (ISSVD) 2003, provoked discomfort and/or pain triggered by sexual or nonsexual contact (intromission, clothing pressure, tampon insertion, fingertip pressure, q-tip pressure, etc.) [1] and ability to understand Scandinavian languages. Diagnostic subsets of PVD, such as primary or secondary, localized or

generalized, with and without primary and secondary vaginismus were included. Exclusion criteria were pregnancy and inability to contract the pelvic floor muscles correctly. All referred patients had a test (microscopy directly or cultivation) for candida and participants with positive test were excluded. Pain during intercourse was an exclusion criterion in the control group.

Power calculation was based on a study with 300 nulliparous pregnant women at 20 weeks of gestation, VRP: 43.0 cm $H_2O$ (SD 9.8), PFM strength: 35.5 cm$H_2O$ (SD 18.0) and PFM endurance: 245 (SD 133.8) [18]. When planning this study, there were no vaginal pressure data from patients with provoked vestibulodynia available. Clinical experience from working with pelvic floor examination of women with pain (PVD) made us assume that vaginal pressure at rest is higher among women with PVD than for urinary incontinent women. We therefore used the difference in cm $H_2O$ (6.6) that had been found in strength between urinary incontinent and continent women. With a two-tailed test, significance level $<0.05$, and power 80%, at least 35 participants are required in each group.

## Procedure

All participants were informed by a physical therapist (IN) about the questionnaires and the vaginal examinations, including an overview of the q-tip pressure points on a chart. After completing the questionnaires, observation and vaginal palpation were performed by the physical therapist (IN) to assess and give feedback on the PFM contraction, ensuring all participants were able to perform a correct PFM contraction.

Vaginal pressure measurement was performed, followed by a q-tip test, and finally sEMG was performed by a trained women's health physical therapist who was unaware towards which groups the participants belonged to. In order to mask the examiner for pain expression, a non-transparent curtain covered the head and the upper body of the participants, while the lower body and legs were visible. The participants were told not to communicate, except when asked to rate the NRS. Data were collected in one physical therapy outpatient clinic in Norway from May 2012 to October 2012. Only newly referred patients were included, and all measurements were done at the first consultation.

Data collection

Background variables and symptoms were collected at the same time point as the clinical evaluation through interviews using questions modified from a comprehensive questionnaire from the Vulva Clinic at Oslo University Hospital. Data included several different self-reported measures, such as onset and duration of symptoms, frequency of yeast infections, urinary and bowel symptoms, use of contraceptives, physical activity level and PFM exercise habits.

Sensitivity of the vulva

A q-tip built into a cylinder attached to a balloon catheter and a high precision pressure transducer were used to assess the pressure applied to provoke pain and/or discomfort in the vulvar vestibule (Reggie q-tip test, Camtech As, Sandvika Norway). The instrument has not yet been tested for intra- and inter-rater reliability, but repetitive testing with different loads in the same women showed reproducible results except for values below 3 grams and applied forces of more than 500 grams. The device was tested in 20 PVD patients. It was well tolerated, and the method was found to be easy to use. The pressure was set at three vestibular sites; 4, 6 and 8 o'clock according to Haefner et al. [19]. Q-tip test was measured in grams

and used to quantify the force used when pressure were set against the skin (mucosa). Participants were told to say “stop” when their pain limits were reached. Pain was registered with the numeric rating scale (NRS) ranging from 0 to10, 0 being no pain at all, 10 being worst ever. Measures were obtained directly after each pressure application.

Ability to perform a correct pelvic floor muscle contraction

The ability to perform a correct PFM contraction, defined as a squeeze around the pelvic openings and a lift of the perineum, was assessed through visual observation and vaginal palpation [13].

Primary outcome measures

Manometer

The vaginal measurements of PFM function (vaginal resting pressure, PFM strength and endurance) were done with a high precision pressure transducer connected to a balloon catheter, balloon size 6.7 × 1.7 cm, (Camtech AS, Sandvika Norway). The method has been tested for intra-observer reliability, and has shown to be reliable [14].The balloon was placed with the center of the balloon 3.5 cm from the introitus [15]. All measurements were done in supine crook-lying position (patient is lying on her back-with bent knees and feet on the bench). Vaginal resting pressure was measured as the difference between atmospheric pressure and the vaginal pressure at rest, without any voluntary PFM contraction and registered as cm $H_2O$ [20]. PFM strength was measured by subtracting the maximal value from resting values and calculated as the mean of 3 maximal voluntary contractions (MVC) registered as cm $H_2O$, and PFM endurance was defined as a sustained maximal contraction and quantified during the first 10 seconds and reported as the area under the curve as sec$H_2O$

[20]. Contractions were considered correct when a visible inward movement of the catheter/perineum was observed simultaneous with the voluntary PFM contraction [14;15].

Surface Electromyography (sEMG)

Intravaginal surface EMG (sEMG) was used to measure electrical activity in the pelvic floor muscles (nerve conduction in a group of muscles). PFM activity, unit microvolt (μV), was measured with NeuroTrac ETS™ sEMG signal processing unit (Verity Medical Ltd, UK). The accurate range is 0.2microvolts (μV) to 2000μV. Sensitivity is 0.1μV root mean square with an accuracy of 4% of the μV reading.

The sEMG probe used was the Anuform™ anal probe, provided by Neen, Mobilis Health Care Group, United Kingdom. The Anuform™ anal probe is a single-patient probe. Due to reported discomfort during insertion of a vaginal probe [11], a smaller anal probe was chosen. The electrodes on the Anuform are 21.5 mm apart and size is 3 $cm^2$ per electrode, longitudinally oriented. The anal probe was inserted vaginally with the electrodes placed in the 3 and 9 o'clock positions and the ring in a vertical position.

PFM activity at rest was measured as vaginal resting sEMG activity before instruction to voluntarily contract the PFM, and calculated as the mean of three periods before contraction. PFM activity was then measured during attempts of MVC and during an attempt to hold the contraction. Peak activity was calculated as the mean of three MVC. PFM activity was measured during the first 10 seconds (μV Sec). sEMG assessment has demonstrated good test-retest reliability in healthy women [21]. All measurements were done in supine crook-lying position.

Statistical analysis

The Statistical Package for Social Science (SPSS), version 20.0 (SPSS Inc., Chicago, IL, USA), was used for statistical analyses. Background variables and symptoms of PVD are reported as numbers of women with percentages or means with standard deviation (SD). Pearson product-moment correlation coefficient was used to assess the correlation between perceived pain on NRS-score and q-tip pressure. PFM variables are reported as means with SD and differences between cases and controls are analyzed using T-test and reported as means with SD. P-value $< 0.05$ was considered statistically significant.

## RESULTS

Seventy-eight women were recruited for the study. Three women in the control group were excluded due to pain during intercourse, another three because of previous pregnancies, and two were excluded due to language difficulties. Thus, the final sample consisted of 70 Scandinavian women, 35 in each group. Background variables are shown in Table 1. There were no statistically significant differences in any of the demographic or health variables between the groups. The PVD group showed a trend towards more candida.

PVD symptoms ranged from 6 months to 4 years for 68% in the PVD group, 29% reported signs of PVD lasting more than 4 years and 2 women reported to have PVD less than 6 months.

The PVD group tolerated significantly lower pressures at three sites of the vulvar vestibule, 4, 6 and 8 o'clock, compared to the control group and had significantly higher pain scores at all sites (Table 2). When analyzing the whole sample (n=70), there was a small, negative correlation between pressure in grams set by Reggie q-tip and experienced pain only at the 4

o'clock site (first tested site); r=-.244, p=0.04. When splitting the sample into PVD and healthy controls, no significant correlation was found.

### Manometer

The PVD group had significantly higher VRP before the first PFM contraction. No statistically significant differences were found in PFM strength or endurance between groups (Table 3).

### Surface EMG

No statistically significant differences were found in resting or peak activity. The PVD group had significantly lower muscle activity during the 10 second holding period (Table 4).

## DISCUSSION

Women with PVD had a higher VRP than healthy controls. However, this was not supported by sEMG resting activity. Measured by sEMG, the PVD group had significantly lower muscle activity during the10 second holding period. There was no statistically significant difference in PFM strength or endurance measured with vaginal pressure or peak sEMG activity during attempts at maximal contraction. We hypothesized that VRP and resting sEMG would be higher in women with PVD compared to healthy controls. As our two measurement methods gave different results and the clinical relevance of the difference found by the pressure transducer can be questioned, our results must be interpreted with caution.

The present study has some limitations. At the time of planning this study there was no commercial assessment tool available in Norway for measurement of discomfort/pain in the vulvar vestibule. Hence, a new instrument was developed. The technology used in the q-tip test is the same as that used in measuring vaginal pressure (Camtech AS, Sandvika Norway),

which has been found to be reliable and valid [14;15]. However, it is necessary to conduct test-retest and intra- and inter-observer reliability studies of this new measurement method. Unfortunately, the study is missing data for sexual function. There is a scope for recall bias in prospective comparison studies [16]. In this study we matched the group of cases with the group of controls, and the data is collected at one time point. One strength is the sample which was a homogenous group; 70 women, all nulliparous and with age ranging between 18 and 38 years. The participants were diagnosed by gynecologists according to current guidelines and our clinical q-tip test confirmed the diagnosis. Further strengths of the present study are the a priori power calculation done for the main analysis with vaginal pressure, thus the study should include sufficient number of participants to provide adequate statistical power. Another strength is masking of the assessors. The physiotherapists assessing the patients had long experience in assessing pain patients and did this in the same way for all participants. As pain may lead to a withdrawal reflex, this may have been observable for the physiotherapist performing the test. However, pain response can occur in all participants, the physical therapists were experienced in handling PVD and other pelvic pain patients and used very gentle techniques when performing the q-tip test and inserting the devices. In addition we used a high-precision pressure transducer found to be responsive, reliable and valid [14;15]. Results from test-retest reliability in healthy volunteers and women with anal insufficiency have found a high intraclass correlation coefficient using the same sEMG device and anal probe as in our study. However, in spite of acceptable reliability, the validity of sEMG can be questioned, mostly due to the high risk of cross-talk from nearby muscle groups [22]. In the present study the participants were instructed to avoid co-contractions of the gluteal, hip adductor and abdominal muscles and all participants had thorough instruction, with vaginal palpation, in how to perform the contractions before the assessments. If co-contractions were observed, practice continued until no co-contraction was performed.

Non-masked studies using vaginal palpation compared to controls have found overactivity of the PFM in women with PVD [4;8;10;11]. However, the responsiveness, reliability and validity of vaginal palpation for measurement of activation of the PFM have been challenged [23]. Kavvadias et al. [24], investigating PFM tenderness of healthy nulliparous young women, found poor reliability while Reissing et al. [9] found that palpation had almost perfect correspondence in discriminating between PVD and healthy controls. Our study showed no significant differences in sEMG between women with PVD and controls in resting or peak activity. This finding is contradictory to other studies [9;10;25], but in accordance with the study by Engman where no difference between groups except for the lower values in the PVD group of 60 second holding activity was found [11]. Our study confirms a significantly lower activity over the 10 seconds holding time in the PVD group, which also corresponds with the findings by Polpeta et al. [26]. The contradictory results between studies may be explained by methodological and comparison challenges between palpation, pressure registration and sEMG measurements [13].

To the best of our knowledge, only one study has reported on VRP in women diagnosed with PVD [26]. This study found no significant differences between women with and women without PVD in VRP, PFM strength or endurance, while the present study found a significant difference in VRP. Elevated VRP might be maintained passively due to inelasticity of vaginal soft tissue [10]. In the study by Polpeta et al. [26] the control group had a higher VRP than the PVD group, whereas sEMG resting activity was slightly higher in the vulvodynia group, which is contrary to our findings. Diversity in findings might be due to non-masking of the assessors, inclusion of parous women and use of a different device to assess VRP, PFM strength and endurance [27]. Thus, the results are not directly comparable.

A possible link between the significant findings of low muscular activity during sustained contraction and the elevated VRP in the PVD group in the present study, can be hypothesized to be due to the elevated VRP requiring sustained muscular activity [28], which might lead to muscular fatigue [29]. However, despite this lower muscle activity in the PVD group, endurance measured by the pressure device did not differ between the groups. The observed VRP could be linked to "the guarding response" described by Reissing et al. [9].

At present, the nature of the relationship between muscular overactivity and muscle pain is under debate. A study comparing patients with Tension-Type Headache with controls found no difference between groups in the muscular activity of the neck muscles measured with sEMG during cognitive stress [30]. Engman et al. questioned whether the increased tone observed clinically ought to be of a another origin than elevated PFM activity [11]. Some of the results from our study are in line with those of Engman et al. Although we found a statistically significant difference in VRP, is it difficult to know if a difference of only three $cmH_2O$ is of clinical relevance, especially as it was not confirmed by the sEMG resting activity. Since the present design cannot rule out causality we hypothesize that reduced muscular endurance may be due to elevated resting pressure. Hence reduction of resting pressure may be important before starting PFM strength or endurance training. However, this theory needs to be tested in a RCT.

## CONCLUSION

Young, nulliparous women with PVD had significantly higher vaginal resting pressure measured with a pressure transducer, but this finding was not supported by vaginal surface EMG. The PVD group had significantly lower PFM activity measured by surface EMG during attempts to hold a PFM contraction, but their ability to hold for 10 seconds was not

different measured by a pressure transducer. No difference between the groups in strength measurement either with pressure or surface EMG was revealed.

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Table1. Background and health variables for the whole study sample (N=70) and for women with provoked vestibulodynia (PVD) and controls.

| | N=70 | PVD N=35 | Controls N=35 | P value of difference between groups |
|---|---|---|---|---|
| Age (years) | 24.3(4.7) | 24.5(4.7) | 24.1(4.7) | 0.71 |
| BMI (kg/m$^2$) | 22.0(2.6) | 21.84(2.9) | 22.2(2.3) | 0.56 |
| Social status (n) | | | | 0.46 |
| Single | | 8 | 12 | |
| Married/Cohabiting | | 22 | 12 | |
| Boyfriend | | 5 | 10 | |
| Educational level (n) | | | | 0.11 |
| University/colleg≥4years | | 30 | 33 | |
| University/college <4years | | 5 | 2 | |
| Work (n) | | | | 0.12 |
| Full-time student | | 4 | 10 | |
| Working part-time | | 20 | 16 | |
| Working full-time | | 11 | 8 | |
| General exercise level (n) | | | | 0.17 |
| No exercise | | 5 | 2 | |
| Once a week | | 9 | 7 | |
| 2-3 times weekly | | 13 | 15 | |

| | | | | |
|---|---|---|---|---|
| >3 times weekly | | 8 | 11 | |
| Use of contraception (n) | | | | 0.12 |
| None | 14 | 7 | 7 | |
| Condom | 11 | 9 | 2 | |
| Oral | 33 | 13 | 20 | |
| Long-acting reversible contraception(LARC) | 11 | 6 | 5 | |
| Numbers performing PFM exercise at present? | | | | 1.0 |
| Yes | | 7 | 7 | |
| No | | 28 | 28 | |
| Candida last 3 years (n) | | | | 0.06 |
| Yes | | 27 | 19 | |
| No | | 8 | 15 | |
| Urinary tract infection last 3 years (n) | | | | 0.34 |
| Yes | | 22 | 18 | |
| No | | 13 | 17 | |
| Urinary incontinence (n) | | | | 0.73 |
| Yes | | 5 | 4 | |
| No | | 30 | 31 | |
| Flatus incontinence (n) | | | | 0.14 |
| Yes | | 6 | 2 | |
| No | | 29 | 33 | |

Means with standard deviations (SD), numbers of women or percentages of each group, PFM=pelvic floor muscle.

Table 2. Pressure in grams (g) and pain reported on a numeric rating scale (0-10) during q-tip test in women with provoked vulvodynia (PVD) and controls.

| | PVD N=35 | Controls N=35 | P-value of difference between groups |
|---|---|---|---|
| 4 o'clock site | | | |
| Pressure (g) | 64.9(46.0) | 95.1(44.5) | 0.01 |
| Pain | 5.5(2.5) | 3.1(2.1) | <0.01 |
| 6 o'clock site | | | |
| Pressure (g) | 92.8(47.1) | 115.6(33.0) | 0.02 |
| Pain | 5.3(2.3) | 3.4(2.1) | <0.01 |
| 8 o'clock site | | | |
| Pressure (g) | 60.7(37.9) | 80.7(41.4) | 0.04 |
| Pain | 4.9(2.7) | 2.9(2.0) | 0.01 |

Means with standard deviations (SD).

Table 3. Pelvic floor muscle (PFM) pressure measurements for the whole group, in the provoked vulvodynia (PVD) and in the control group. Vaginal resting pressure (VRP) before the first contraction, PFM strength expressed as mean of three maximum voluntary contractions (MVC) and muscular endurance defined as a sustained maximal contraction quantified during the first 10 seconds of the contraction.

| | N=70 $cmH_2O$ (SD) | PVD N=35 $cmH_2O$ (SD) | Controls N=35 $cmH_2O$ (SD) | P-value between groups |
|---|---|---|---|---|
| VRP before the first MVC (cm $H_2O$) | 18.9(6.1) | 20.6(7.1) | 17.3(4.4) | 0.02 |
| PFM strength (mean of 3X MVC) (cm $H_2O$) | 18.1(11.9) | 17.2(13.2) | 18.9(10.6) | 0.57 |
| PFM endurance (10sec$H_2O$) | 141.3(95.4) | 126.8(96.9) | 155.7(93.0) | 0.21 |

Means with standard deviations (SD).

Table 4. Vaginal surface EMG of the pelvic floor muscles (PFM) in the whole group, the provoked vestibulodynia (PVD) and control group. Activity at rest before the first maximum voluntary contraction (MVC), peak activity expressed as the mean of three MVC and endurance expressed as the ability to hold the contraction for 10 seconds.

| | N=69 µV(SD) | PVD N=34 µV(SD) | Controls N=35 µV(SD) | P-value between groups |
|---|---|---|---|---|
| Activity at rest before the first MVC | 15.2(12.7) | 13.5(7.1) | 16.9(16.4) | 0.28 |
| PFM peak activity | 52.7(24.3) | 48.5(21.6) | 56.8(26.4) | 0.15 |
| PFM endurance (10sec µV) | 529.0(256.4) | 465.2(218.4) | 591.1(277.7) | 0.04 |

Means with standard deviations (SD).