



Reliability and Reproducibility of Novel Methodology for Assessment of Pressure Pain Sensitivity in the Pelvic Region

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Introduction

- Vestibulodynia, the most common type of chronic vulvovaginal pain, affects nearly 1 in 10 women at some point in their lifetime¹
- Current clinical diagnostic criteria for vestibulodynia dates back to Friedrich's case series of 86 patients published in 1987² which include 1) entry dyspareunia (painful intercourse), 2) tenderness to pressure within the vestibule, and 3) physical findings limited to erythema without other obvious pathology²
- Friedrich's criteria is limited to evaluation of the vulvar vestibule-unlike mucosa, the spectrum of normal and abnormal tenderness in the pelvic floor and its constituent muscles (e.g. puborectalis muscle) has not been described
- Although the body of literature on vestibulodynia has expanded, no revised criteria including beyond Friedrich's initial description to include pelvic floor dysfunction have been formulated
- Our hypothesis is that vestibulodynia is a heterogeneous disorder and that mucosal and muscle pain sensitivities can be used to identify distinct subgroups of patients
- The purpose of this study was three fold: 1) to develop instrumentation and methodology for the objective assessment of vulvar mucosal and pelvic muscle sensitivities, 2) to establish a standardized clinical approach for assessing pain sensitivity in vulvar mucosa and pelvic musculature, and 3) to relate these measures to patients' clinical pain reports

Methods

- 34 women with vestibulodynia and 21 pain free controls were recruited through an institutional review board-approved protocol at the University of North Carolina, Chapel Hill between March 2006 and August 2009
- The exam consisted of a standardized pain sensitivity assessment of precisely located vulvar mucosal and pelvic muscle sites (Fig.1)
- Reliability was assessed by a repeat exam during the same session by a second examiner, or by one or two of the same examiners in a separate session approximately two weeks later
- Instrument reliability was assessed by calculating Pearson correlations between each pair of measurements
- The association between each measurement and vestibulodynia case status was evaluated using Cox proportional hazards models
- Some measurements were terminated by the examiner before the appropriate threshold was reached, resulting in right censored data which necessitated the use of the Cox model
- A random effect for each subject was included in the models to account for repeated measurements.

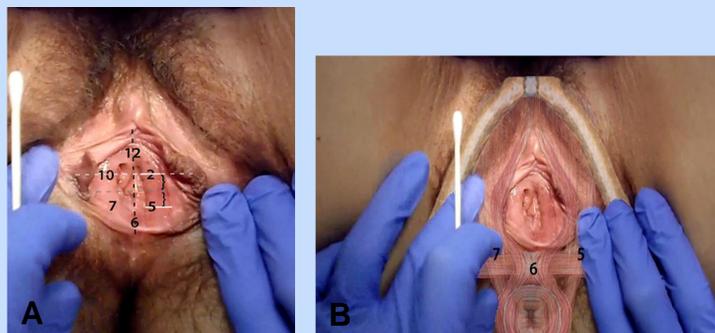


Figure 1. A) Location of pain sensitivity assessment of the vulvar vestibule and B) underlying pelvic musculature

- In collaboration with the biomedical engineering core at the Center for Neurosensory Disorders at the University of North Carolina in Chapel Hill, an algometer for pressure pain sensitivity of the vulvar vestibule and the underlying pelvic musculature (Fig 2)
- For the assessment of the vestibule a digital algometer (Wegner instruments®) was affixed to a disposable cotton swab and a custom-built computer interface for real time data acquisition (Fig. 2A)
- Upon initiation of contact with the vestibular mucosa, the examiner(s) began application of pressure at an approximate rate of 1 N per second
- Subjects were instructed to click a computer mouse upon the first sensation of pain, at which point the pressure was immediately terminated and automatically recorded as the "mucosal pressure pain threshold" (Fig. 2B)
- Each mucosal site was examined three times with an inter-stimulus interval (ISI) of 2 seconds
- A verbal command via a computer interface announced the order of sites, number of repetitions (3 per site), and the interval between the palpations of individual sites and repetitions within each site
- A typical exam consisted of a verbal command to start at site 2, and after obtaining three threshold values (with an ISI of 2 seconds) the examiner was prompted to move to sites 10, 12, 5, 7, and 6 sequentially

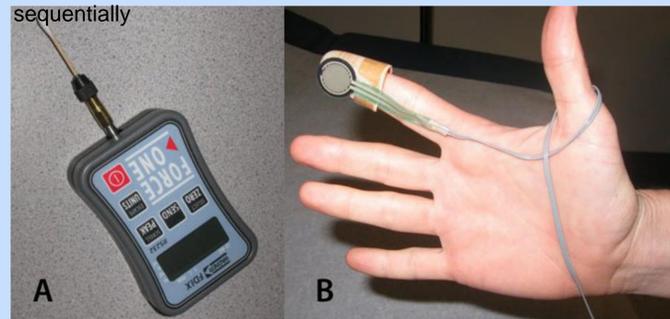


Figure 2. A) Wegner instruments® digital algometer with affixed disposable cotton swab B) Computer mouse controlled by subject, initiated upon the first sensation of pain

Results

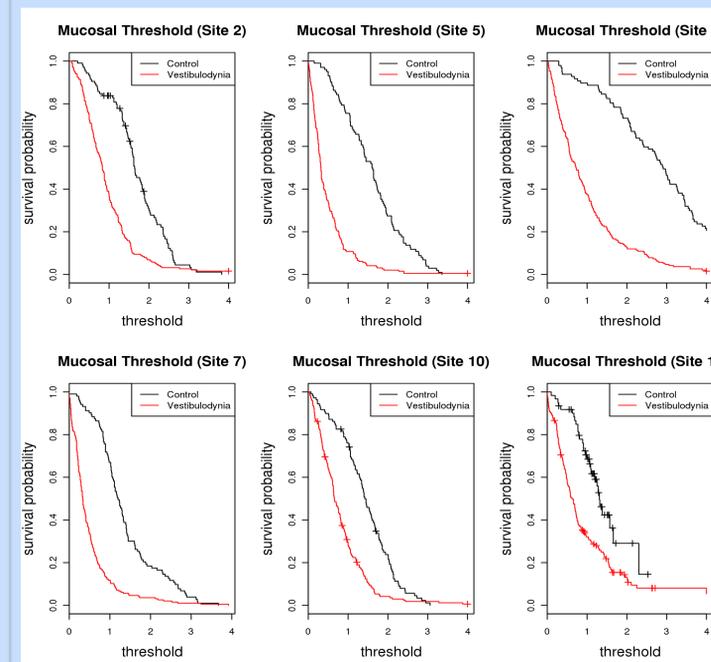


Figure 3. Kaplan-Meier Plots for Vulvar Mucosal Pressure Pain Detection Threshold. The curves show an estimated probability of terminating the exam prior to a given amount of force for controls and vestibulodynia patients.

- Overall, women with vestibulodynia showed significantly lower mucosal pressure pain thresholds compared to their pain-free counterparts
- This was particularly robust at the three sites on the lower vestibule (HR=17-46), although the upper vestibule measurements were also strongly associated with vestibulodynia (HR=6-7)
- Similarly, compared to pain-free participants, patients with vestibulodynia showed lower pelvic muscle pressure pain threshold and tolerance measurements
- A significant association was noted between vestibulodynia case status and muscle threshold measures when measurements from all three sites were combined (HR=2.9, p=0.047)
- Individually, sites 5 (HR=4.9) and 7 (HR=9.3) were significantly associated with case status, although no association was observed at site 6
- There was a similar pattern of association with respect to the muscle tolerance measures when measurements were combined across the three sites (HR=3.09, p=0.005)
- Only site 5 was significantly associated with case status individually (HR=6.3), although the associations at the other two sites were nearly statistically significant (HR=4.8 at site 6 and HR=3.0 at site 7)
- Of the tested vestibular mucosal sites (six), only three lower vestibular sites (5, 6, and 7) were associated with intercourse-related pain
- Measures of muscle pain sensitivity were not associated with participants' self-reported pain during intercourse, despite being associated with case status

- Within-examiner correlations were high (r=0.81-0.87) for both mucosal and muscle sites
- On average mucosal and muscle measures were stable over a two-week period
- The highest between-visit correlations were observed at the three lower mucosal sites (r=0.82-0.87). The correlations for the remaining three mucosal (r=0.55-0.66) and muscle sites (r=0.61-0.67) were lower
- Between-examiner correlation on average was lower (r=0.11-0.58) for the mucosal sites, but within acceptable range for the respective muscle sites (r=0.58-0.85)
- Only one mucosal site (6 o'clock) reached an acceptable inter-examiner correlation (r=0.577)
- The six o'clock site was also the only site tested for which the perpendicular application of pressure using a cotton swab could be conducted under direct visualization with a high degree of manual accuracy
- On average the inter-examiner correlations for muscle were higher than those for the mucosa; the highest correlation for muscle was seen at the 7 o'clock position, likely attributed to the right-handed examiner's ability to apply pressure in an anatomically congruent manner (right handed examination of the patient's right pelvic muscle)
- As muscle tolerance measures are a reflection of examiner's maximal force, lower correlation between the two examiners was observed for pain tolerance than for pain detection thresholds
- The lower inter-examiner reliability, particularly for mucosal assessment, highlights the importance of training and calibrating the examiners

Conclusions

- Mucosal and muscle threshold measures remained highly stable over the two weeks study period, with high within-examiner correlation
- Both sets of measurements were also associated with vestibulodynia case status, offering the hope of a more precise case definition for vestibulodynia and related disorders
- Our data support the feasibility of concurrent assessment of vulvar mucosa and underlying musculature in the pelvic region

Bibliography

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