A randomized clinical trial evaluating the efficacy of multimodal physical therapy in comparison to overnight topical lidocaine in women with provoked vestibulodynia

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Context

• Vulvodynia: prevalence 7-8% (Harlow, 2014)
• Provoked vestibulodynia (PVD) is considered the leading cause of vulvodynia
• It has significant deleterious repercussions on sexual function and relationship difficulties (Desrochers, 2008; Payne, 2005; Arnold 2006)
Context

- **Multimodal physical therapy**
  - Recommended as a first-line treatment (ACOG, 2006, Mandal, 2010; Stockdale 2014; Goldstein 2016)
  - Ranked by experts among the most effective treatments (Reed, 2008)
  - Its efficacy has only been evaluated through three small uncontrolled or pilot trials (Bergeron 2002; Goldfinger 2009, 2016)

SEXUAL MEDICINE REVIEWS

Systematic Review of the Effectiveness of Physical Therapy Modalities in Women With Provoked Vestibulodynia

Mélanie Morin, PT, PhD, Marie-Soleil Carroll, MA, and Sophie Bergeron, PhD

There is a need to assess the efficacy of this promising treatment

Context

- **Lidocaine**
  - Lidocaine is considered among the first line treatments for PVD (ACOG, 2006, Mandal, 2010)
  - Lidocaine is among the most commonly used treatment by experts in vulvodynia (Reed, 2008)
  - The overnight protocol application of lidocaine treatment was found effective in women with PVD (Zolnoun, 2003)
Objectives

Primary objective
• To evaluate and compare the efficacy of multimodal physical therapy and overnight topical lidocaine in reducing pain intensity during intercourse in women with PVD

Secondary objectives
• To compare the efficacy of both interventions for:
  ➢ Pain quality
  ➢ Sexual distress and sexual function
  ➢ Patient’s satisfaction and global impression of change

Study design

Bi-center randomized controlled trial (Sherbrooke and Montreal, Canada)
Women with diagnosed PVD

Baseline assessment, consent, randomization

Multimodal physical therapy  Overnight lidocaine application

Post-treatment

6-month Follow-up
Methodology - Participants

- Women diagnosed with PVD following a standardized protocol including the Q-tip test (Bergeron, 2001)

**Inclusion**
- Nulliparous
- 18-45 years old
- Pain limited to the vestibule during intercourse and activities exerting pressure
- Pain intensity ≥5/10, ≥90% of attempts

**Exclusion**
- Other gynecological pain conditions
- Active urinary or vaginal infection (or in the last 3 months)
- Past vulvar or vaginal surgery
- Previously received physio or overnight lidocaine

Methodology

**Primary outcome**

- Average pain intensity during intercourse: Numerical Rating Scale (NRS) from 0 (no pain) to 10 (most intense pain)

Methodology

Secondary outcomes

- **Pain quality**: McGill Pain Questionnaire (Melzack, 1975)
- **Sexual function**: Female Sexual Function Index (Rosen, 2000)
- **Sexual distress**: Female Sexual Distress Scale (Desrogatis, 2002)
- **Satisfaction**: from 0 not satisfied to 10 fully satisfied
- **Patient’s Global Impression of Change**: 7-point scale, very much improved to very much worse (Farrar, 2001)


Methodology- Intervention

**Multimodal PFM physical therapy**

- 10 weekly sessions supervised by experienced physical therapists
- Each session consisted of (According to Bergeron, 2002; Hartmann, 2007)
  - Education (e.g. pathophysiology, relaxation techniques, etc.)
  - Manual techniques
  - Biofeedback (relaxation, strength, endurance and coordination)
  - Insertion techniques
  - Home exercise program 5 days/week
Methodology - Intervention

Topical overnight lidocaine
• 5% lidocaine ointment (50mg/g, Lidocan®, Odan Lab, 35g) to the vestibule every night for 10 weeks according to Zolnoun et al. (2003)

Methodology

Sample size
• 170 women were needed to detect a clinical significant difference of 1.5, SD 3.47 (Bergeron 2002), alpha 0.05, power 80% - we targeted 212 to account for a dropout rate of 20%.

Blinding
• Evaluators and data analysts were blinded to group assignation

Statistical analysis
• Analyses were performed based on the intention-to-treat principle.
• A multilevel model of change (growth model) was used to evaluate and compare the efficacy of the interventions (Vickers, 2001; Singer, 2003)
Results - Trial flow

521 women interested in participating
- Eligible and randomized (n=212)

Multimodal physical therapy (n=105)
- 99 completed post-treatment
  - 6 discontinued intervention
  - 1 psychiatric condition
  - 1 moving
  - 4 time constraint

Lidocaine (n=107)
- 102 completed post-treatment
  - 5 discontinued intervention
  - 1 allergy to lidocaine
  - 1 travel
  - 3 time constraint

Results - Baseline

<table>
<thead>
<tr>
<th></th>
<th>Physical therapy (n=105)</th>
<th>Lidocaine (n=107)</th>
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<tbody>
<tr>
<td>Age (years)</td>
<td>23 (5)</td>
<td>23 (4)</td>
</tr>
<tr>
<td>Pain intensity (NRS/10)</td>
<td>7.3 (1.5)</td>
<td>7.3 (1.5)</td>
</tr>
<tr>
<td>Duration of symptoms (years)</td>
<td>4.3 (3.5)</td>
<td>3.9 (3.2)</td>
</tr>
<tr>
<td>Frequency of intercourse (per month)</td>
<td>5 (6)</td>
<td>5 (5)</td>
</tr>
<tr>
<td>Use of oral contraceptive (%)</td>
<td>85 (81%)</td>
<td>85 (79%)</td>
</tr>
<tr>
<td>Type of PVD</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Primary / secondary</td>
<td>38% primary / 62% secondary</td>
<td>31% primary / 69% secondary</td>
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Results expressed in mean (standard deviation) or frequency (%)
**Results - Primary outcome**

**Pain intensity (NRS)**

- Adjusted mean ± standard error. ***p<0.0001

**Pain quality (McGill Pain Questionnaire)**

- Adjusted mean ± standard error. ***p<0.0001
### Results - Secondary outcomes

#### Physiotherapy vs. Lidocaine

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<tr>
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<th>Physiotherapy</th>
<th>Lidocaine</th>
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<tbody>
<tr>
<td></td>
<td>Baseline</td>
<td>Post-tx</td>
</tr>
<tr>
<td>Sexual distress</td>
<td>31.8 (1.1)</td>
<td>12.4 (1.1)</td>
</tr>
<tr>
<td>Sexual function</td>
<td>21.1 (0.8)</td>
<td>28.9 (0.4)</td>
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*Adjusted mean ± standard error. ***p<0.0001*

Over the clinical cut-off for sexual dysfunction (Wieger, 2005)

#### Satisfaction

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<tr>
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<th>Physio</th>
<th>Lido</th>
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<tbody>
<tr>
<td>Post-treatment</td>
<td>8.9</td>
<td>5.6</td>
</tr>
<tr>
<td>6-month follow-up</td>
<td>8.5</td>
<td>5.3</td>
</tr>
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*p<0.001*

### Patient’s global impression of change

- Women reported being very much or much improved:
  - 77% of women in the physical therapy group compared to 38% in the lidocaine group *(p<0.001)*
Conclusion

• Multimodal physical therapy is effective in reducing pain and sexual distress as well as improving sexual function in women with PVD.

• This information is important for clinicians and women in terms of management strategies.

Multimodal physical therapy proved to be more effective than a frequently used first-line treatment - overnight lidocaine topical application.

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Thank you!