Reduction of Chronic Abdominal and Pelvic Pain, Urological and GI Symptoms
Using a Wearable Device Delivering Low Frequency Ultrasound

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Summary

PainShield®, a portable, wearable ultrasound device was found to reduce pelvic, urological pain and related symptoms in 19 patients presenting with long-standing and refractory symptoms.

Objective

To assess the efficacy of Painshield for pelvic and related pain.

Methods

Design: Open-label, prospective, experiential study
Patients: 16 women and 3 men (age 46, range 33–62)
Inclusion criteria: Age > 18 years
Doctor or PT prescription/order
History of chronic pelvic, urological or related pain or symptoms, refractory to other treatment
Exclusion criteria: Malignancy, known sensitivity to ultrasound
Time from first Dx: 15.3 years, range 1–33 years
Diagnoses:

- Adhesions: 63%
- Bowel obstruction: 42%
- Endometriosis: 26%
- IBS: 32%
- Interstitial Cystitis: 32%
- Other Chronic Pelvic Pain: 63%

Sitting tolerance time (mins)
Before Tx
6.9
After Tx
7.8
P = 0.090

Painshield Driver and Patch

Therapeutic Ultrasound
- Ultrasound widely known for effects in pain relief, muscle spasm and wound healing
- Low frequency, low intensity ultrasound shown to reduce pain & biofilm formation, increase wound healing via possible effects on nerves, blood vessels and nitric oxide formation

Painshield
- Thin 3cm transducer in self-adhering, portable and wearable patch
- Efficacy shown in trigeminal neuralgia and other pain conditions
- Penetration of US energy of up to 4 cm below the surface and therapeutic action reaching up to 20 cm from the device

Results

<table>
<thead>
<tr>
<th>Symptom</th>
<th>Maximum pain or symptom score</th>
<th>N</th>
<th>P</th>
</tr>
</thead>
<tbody>
<tr>
<td>Bladder pain before urination</td>
<td>Before Tx: 6.1 After Tx: 4.3</td>
<td>12</td>
<td>0.021</td>
</tr>
<tr>
<td>Pain on urination</td>
<td>6.0</td>
<td>7</td>
<td>0.001</td>
</tr>
<tr>
<td>Urinary urgency (% of time)</td>
<td>100%</td>
<td>54%</td>
<td>0.060</td>
</tr>
<tr>
<td>Urination frequency (day)</td>
<td>21</td>
<td>11</td>
<td></td>
</tr>
<tr>
<td>Difficulty urinating (% of time)</td>
<td>100%</td>
<td>60%</td>
<td>0.080</td>
</tr>
<tr>
<td>Other Chronic Abdominal or Pelvic Pain</td>
<td>8.3</td>
<td>5.9</td>
<td>0.042</td>
</tr>
<tr>
<td>Dyspareunia, during</td>
<td>7.8</td>
<td>5.5</td>
<td></td>
</tr>
<tr>
<td>Dyspareunia, after</td>
<td>6.6</td>
<td>4.3</td>
<td></td>
</tr>
<tr>
<td>Dyschezia</td>
<td>7.7</td>
<td>3.6</td>
<td>0.001</td>
</tr>
<tr>
<td>Abdominal bloating (% of time)</td>
<td>83%</td>
<td>53%</td>
<td>0.049</td>
</tr>
<tr>
<td>Rectal Pain</td>
<td>9.3</td>
<td>6.0</td>
<td></td>
</tr>
<tr>
<td>SI-Joint Pain</td>
<td>8.5</td>
<td>6.5</td>
<td>0.081</td>
</tr>
<tr>
<td>Sitting tolerance time (mins)</td>
<td>36.3</td>
<td>90.8</td>
<td></td>
</tr>
<tr>
<td>Other muscle/joint pain</td>
<td>7.4</td>
<td>5.2</td>
<td>0.030</td>
</tr>
</tbody>
</table>

Adverse events

The two patients responding negatively reported a rapid onset (< 1 day) of pain and/or swelling which subsided from 1 to several days later. One patient responding well experienced some abdominal discomfort after using the device. Two of these patients reported similar reactions to conventional office-based ultrasound.

Conclusion

Further evaluation of Painshield for CPP is warranted.

Disclosure

At the time of the study, neither author had a financial interest in the evaluated product. Subsequently DW has formed a company (KevMed) to distribute PainShield for pelvic pain and related conditions.

For full prescribing information please contact:

www.kevmed.com

Acknowledgement

We thank Nanovibronix, Inc. (Nesher, Israel) for providing Painshield units at no cost.

Citation


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