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, experimental 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%

Scoring based on:

Brief Pain Inventory.

Short–Form McGill Questionnaire

International Pelvic Pain Society’s form

Scores collected before and up to 51.4 (range 1–207) days after treatment started.

Comparison: Maximum scores for each type of pain from before and after treatment were ranked and compared (t test).

Treatment: 1-2 sessions/day each consisting of 12 alternating periods (30 minutes) of active and inactive ultrasound energy delivery.

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 Driver and Patch

PainShield

• Thin 3cm transducer in self-adhering, portable and wearable patch

• Efficacy shown in trigeminal neuralgia and other pain conditions

• Conventional units limited by cost, size, portability and availability to offices

• Penetration of US energy of up to 4 cm below the surface and therapeutic action reaching up to 20 cm from the device

Results

Symptom Maximum pain or symptom score N P

Bladder pain before urination 6.1 4.3 12 0.021

Pain on urination 6.0 2.0 7 0.001

Urinary urgency (% of time) 100% 54% 6 0.060

Urination frequency (eday) 21 14 11

Difficulty urinating (% of time) 100% 60% 6 0.080

Other Chronic Abdominal or Pelvic Pain 8.3 5.9 12 0.042

Dyspareunia, during 7.8 5.5 12

Dyspareunia, after 6.6 4.3 8

Dyschezia 7.7 3.6 10 0.001

Abdominal bloating (% of time) 83% 53% 10 0.049

Rectal Pain 9.3 6.0 4

Sacroiliac Joint Pain 8.5 6.5 6 0.081

Sitting tolerance time (mins) 36.3 90.8 12

Other muscle/joint pain 7.4 5.2 18 0.030

Results

• Onset of relief often within hours or days after starting treatment

• Patients rated their overall response as:

  Negative 2/19
  Mild 4/19
  Moderate 3/19
  Good 10/19

• Improvements in pain or related symptoms noted for all symptoms:

  Exceeding Significance (<0.05) 
  Approaching Significance (<0.10)

  • Bladder pain before urination
  • Pain on urination
  • Dyschezia
  • Abdominal bloating
  • Other muscle/joint pain
  • Other chronic pelvic or abdominal pain

  Numerical Reductions
  • Urination frequency
  • Dyspareunia (during or after)
  • Rectal pain
  • Sitting tolerance

• Anecdotal reports of clinically significant:

  • reductions in analgesic and medication usage and cost
  • improvements in sleep due to less pain
  • Effects seen for maximum score mirrored for minimum & average scores, and longer term follow-up
  • Delayed return of symptoms after discontinuation of treatment in several patients with return of effect after resumption

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.

Acknowledgement

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

Citation


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