Ultrasound Therapy for Chemotherapy Induced Peripheral Neuropathy in Colon and Colorectal Cancer Patients: A Pilot Randomized Controlled Trial

Mona Al Onazi\(^1\), PT, MSc. Janice Yurick\(^2\), PT. Claire McKenzie\(^1\), MSc. Neil Chua\(^2\), PT. Margaret McNeely\(^1,2\), PhD.

\(^1\)University of Alberta
\(^2\)Cross Cancer Institute
Chemotherapeutic agents used in the treatment of cancer

Toxic neuropathy affecting the peripheral nervous system

Chemotherapy Induced Peripheral Neuropathy (CIPN)

Sensory symptoms (Tingling, burning, numbness, Reduced sensation, ataxia and falls)

Functional difficulties and Increased risk of falls

What are the available management options?

• In cancer clinical settings, ultrasound therapy used to address pain and other sensory symptoms
• No clinical research studies have been performed examining its efficacy in any patient population with CIPN

Study Objectives:
• To determine the preliminary efficacy of adding therapeutic ultrasound to current standard of care for patients with CIPN
• To determine the point estimates and measures of variability for CIPN-related pain and sensory disturbance
METHODS

Randomized Controlled Pilot Trial

31 Participants

Assessment
- Sensory Disturbance and Pain
  - Protective Sensation
  - Temperature (Hot/Cold)
  - Vibration
  - Achilles Reflex
  - Balance

Randomization

Program

15 Control group
- Home Exercise Program

16 Intervention group
- Home Exercise Program + Ultrasound Therapy
- Home Exercise Program
## RESULTS

### Primary Outcomes

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<tr>
<th>Change: Baseline-2 week</th>
<th>Change: Baseline-6 week</th>
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<td><strong>Control Group</strong></td>
<td><strong>US Group</strong></td>
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<td><strong>6-Week</strong></td>
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### FACTG

- **Baseline**: 1.15 (10.52)
- **Week 2**: -1.17 (9.97)
- **Week 6**: -3.32 (16.48)

### FACTGNTX

- **Baseline**: 0.012 (7.93)
- **Week 2**: -2.71 (12.80)
- **Week 6**: 2.88 (17.70)

### Neurotoxicity

- **Control Group**: 0.09 (6.56)
- **US Group**: 0.60 (4.41)
- **Control Group**: 0.003 (7.60)
- **US Group**: 0.14 (5.53)
- **Control Group**: 0.012 (7.93)
- **US Group**: 0.29 (4.41)

### GCG Percentage

- **Baseline**: 1.15 (10.52)
- **Week 2**: -1.17 (9.97)
- **Week 6**: -3.13 (12.29)
- **Mean (SD)**: 0.93 (10.74)

### Protective

- **Baseline**: 2.00 (4.10)
- **Week 2**: 2.13 (2.81)
- **Week 6**: 2.53 (4.11)
- **Mean (SD)**: 2.17 (4.75)

### Temperature

- **Baseline**: 0.79 (2.61)
- **Week 2**: 2.16 (3.31)
- **Week 6**: 2.04 (4.06)
- **Mean (SD)**: 1.90 (4.79)

### Vibration (Fingers)

- **Baseline**: -0.20 (0.56)
- **Week 2**: 0.31 (0.70)
- **Week 6**: 0.20 (1.42)
- **Mean (SD)**: 0.03 (1.95)

### Balance

- **Baseline**: 0.54 (3.31)
- **Week 2**: 1.88 (7.60)
- **Week 6**: 2.61 (6.46)
- **Mean (SD)**: 1.00 (2.25)
CONCLUSION

• CIPN associated with a broad range of effects to sensory, motor and autonomic systems that affect survivors quality of life
• Adding therapeutic ultrasound to standard care resulted in a **statistical significant improvement** in self-reported symptoms of **pain and sensory disturbance** (\(p < 0.003\))
• The improvement was **more than double** the minimal clinically important difference (10.75 points)
• No significant differences were found at 6 weeks (\(p > 0.05\))
• No significant differences were found in other outcomes with the exception of distal vibration sensation (\(p = 0.03\))

**Study Limitations:**
• Small sample size
• Absence of placebo control group

**Future Research**
• **A large scale placebo-controlled** randomized study is needed to examine the efficacy of therapeutic ultrasound for patients with CIPN