Active Compression Abdominal Binder for Treating Orthostatic Hypotension

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Background

- Orthostatic hypotension (OH) - decrease in blood pressure ≥ 20mmHg/10mmHg in the first three minutes after standing or head up tilt-table testing
  - 6% of US population (~20M patients)
- Symptoms – lightheadedness, dizziness, weakness, syncope, confusion, nausea
- Causes – damage to center and/or peripheral sites in baroreceptor effenter pathway
  - Drug-induced, depletion of total or effective intravascular volume, primary neurogenic, secondary neurogenic
  - Conditions such as Parkinson’s, diabetes, multiple system atrophy, multiple sclerosis, and syringomyelia, among others
- Risks – falls, stroke, cardiovascular diseases
  - 2.5 times greater risk of recurrent falls for individuals with OH compared to elderly counterparts without OH
  - Seen in 52% of advanced and older patients with Parkinson’s disease

Orthostatic Hypotension (OH) Treatment

- Standard of care for OH treatment: four steps
  1. Assess and adjust pre-existing medications
  2. Non-pharmacologic approaches
    - Blood volume repletion
    - Diet (smaller meals, less sodium)
    - Physical conditioning
    - Avoiding increased body temperature
  3. Single-agent pharmacologic approach
  4. Combined pharmacologic treatment
- Most non-pharmacologic approaches have shown limited efficacy
- Knee-high compression garments ineffective
- Low patient compliance with existing abdominal compression garments
  - Require fitting, difficult to put on, and uncomfortable especially in hot climates

Device Specifications

- Active Compression Elastic Abdominal Binder
  - Nylon coated wires span abdomen with mesh-like structure in rear
  - Gear tightening system for secure fit and quick adjustments
  - Force-sensing resistor placed on interior of binder around abdomen
  - Motor systems connected to mobile device and using wearables data for activation parameters
  - Binder size: 68-114 cm
  - Response time <10 s to apply compression within 1.3-5.3 kPa
  - Lightweight, weighing <1 lb

Verification testing

- Prototype constructed using Boa® Fit System Technology
- Compression measured using mannequin
- Achieves reliable, safe compression

Advantages Versus Existing Solutions

- Not designed for OH, minimal improvement in symptoms and in BP
  - Difficult to put on, uncomfortable
- Not designed for OH, improvements in symptoms when worn correctly
  - Typically requires assistance from a second person to put on, uncomfortable
- Designed to be easy to slip on and simple to adjust to comfortable tightness

Market Validation

- Consequences of untreated OH:
  - More fall-related ED visits, hospitalizations, and outpatient visits and services
- Estimated cost savings >$10k per year per patient
  - Fall-related cost savings of successful OH treatment using the drug Droxidopa: $14.5k
  - OH drug market in 2015: $560.9M, expected to increase to $978.5M by 2025
  - Patients with both Parkinson’s Disease and OH have over $10k more costs per year than Parkinson’s patients without OH

References