Introduction

Neuropathic pain (NP) after spinal cord injury (SCI) has a prevalence of 40-50% and is often refractory to available therapies which provide pain reduction of 20-30%, at best. In addition, NP can exacerbate physical disability and decrease quality of life (QOL). Patients have reported willingness to trade potential recovery of strength, bowel, bladder, or sexual function for pain relief.¹

One proposed mechanism causing NP is up-regulation of transient receptor potential vanilloid 1 (TRPV 1) proteins in unjured C fibers and dorsal root ganglia causing increased neuronal excitability. Recent studies have found up-regulation of TRPV 1 receptors after central nerve injury from SCI.²

Capsaicin is a highly selective agonist of TRPV 1 proteins. Capsaicin 8% patch (C8P) is a FDA approved for NP in human immunodeficiency virus autonomic neuropathy and post herpetic neuralgia (PHN).³ A single topical application for 1 hour causes reversible TRPV 1 defunctionalization and 80% reduction in epidermal nerve fiber density. Pain relief after C8P application is reported to last 8-12 weeks and has resulted in a reduction of oral opioid use in these populations. Repeated application defunctionalizes the nerve fibers for prolonged periods of time resulting in more persistent desensitization over time.⁴

In persons with SCI, the efficacy of capsaicin has not been extensively studied. One small study demonstrated efficacy of Capsaicin 5% cream for radiculopathy pain in persons with SCI and 2 case reports showed efficacy for central NP.⁵,⁶

We hypothesize C8P will significantly improve pain, QOL, and function in persons with SCI and 2 case reports showed efficacy for central NP.⁵,⁶ Persistent desensitization over time resulted in a reduction of oral pain medication and polypharmacy, while minimizing adverse systemic effects.

Design

Randomized single-blinded controlled crossover pilot study. The proposed design is a 1 year post spinal cord injury (SCI) in 2 phases. The study will randomly assigns participants to 1 or 2 sequences (Table 1) where A indicates Capsaicin 8% active patch (C8P) and B indicates Capsaicin 0.025% control patch. Each phase is 12 weeks. The patient receives both the active and control patches and is blinded to the patch received.

Inclusion criteria

• > 1 year post spinal cord injury
• SCI levels C2-L1 and AIS A-D
• VAS > 3
• Pain below the level of injury
• Neuropathic pain assessed by the Leeds Assessment of Neuropathic Symptoms and Signs (LANSS) Pain Scale. Defined by LANSS score >12

Exclusion criteria

• Painful area > 1,120 cm² (4 patches per FDA limit)
• History of Capsaicin 8% patch application
• Skin breakdown over area
• Uncontrolled hypertension or autonomic dysreflexia

Outcome measures

• Primary – VAS
• Secondary – SCIM, MPI-SCI, WHO-QOL BREF

Methods

Patch placement (C8P vs. control) is applied at week 0 (baseline).

1. Patient 1: 71y M, C5 AIS D SCI with electrical or burning pain located midline scapular at the levels of T3-T10.
2. Patient 2: 54y F, T5 AIS C SCI with burning or "ants on fire" pain of the bilateral dorsum of the foot.
3. Patient 3: 34y M, T10 AIS C SCI with burning pain to his right lower thigh.
4. Patient 4: 64y M, T1 AIS A with electrical pain located at the left outer thigh.
5. Patient 5: 54y M, C6 ASIA B with pain located at L wrist/thumb
6. Patient 6: 34y M, C4 ASIA B with bilateral anterior thigh pain
7. Patient 7: 45y F, L4 ASIA D with burning and alodynia to R lateral ankle

Pain scores were assessed by the Visual Analog Scale (VAS) at weeks 0 (baseline), 2, 4, 6, 8, 10, and 12.

Three validated surveys were self administered in a face-to-face clinic visit at weeks 0 (baseline), 4, 8, and 12.

- Spinal Cord Independence Measure (SCIM): is a disability scale developed to specifically address the ability of SCI patients to perform basic ADLs independently. The 3 areas evaluated are self care, respiration/spincter management, and mobility.
- World Health Organization Quality of Life (WHO-QOL) denotes the individual’s perception relating to his/her quality of life assessed based on 4 domains: physical health, psychological, social relationships and environment.
- Multidimensional Pain Inventory SCI (MPI-SCI): is designed to assess the impact of and adaptation to chronic pain by evaluating 3 areas: pain impact (section I), responses by significant others (section II) and common activities (section III). Eight of the scales measure cognitive, affective, social, and behavioral responses and four of the scales assess the degree of participation in various types of activities.

Results

Seven persons have completed the protocol to date, statistical power is low, however, findings to date are as follows:

- No significant change in VAS over time.
- Pain relief after C8P application is reported to last 8-12 weeks and has resulted in a reduction of oral opioid use in these populations. Repeated application defunctionalizes the nerve fibers for prolonged periods of time resulting in more persistent desensitization over time.
- Pain scores were assessed by the Visual Analog Scale (VAS) at weeks 0 (baseline), 2, 4, 6, 8, 10, and 12.

Patients have reported willingness to trade potential recovery of strength, bowel, bladder, or sexual function for pain relief.¹

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Capsaicin 8% Patch for Spinal Cord Injury Focal Neuropathic Pain
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P1 was not fluent in English, so surveys had to be filled out with assistant.
P2 underwent a surgical spine procedure that confounded pain scores.
P3 did not correctly fill out SCIM thus this data was not used for statistical analysis

There was no significant difference in VAS scores when comparing control (0.025%) and high dose (8%) capsaicin (C8P). There was improvements in two of the four domains of the WHOQOL, (social relationships and environment) and improvements in four of the 12 domains of the MPI-SCI (life interference, life control, distracting responses, and social activities).

Funding provided by the Texas Chapter of the Paralyzed Veterans of America, Foundation for PM&R, Milbank Award, SCI Rehabilitation

Results (continued)

Table 1

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Support

Pain Severity

Affec<ve Distress Responses

Household Chores

Away Ac<vi<es Home Ac<vi<es Social

Domain 1: Physical Health

Domain 2: Psychological

Domain 3: Social Relationships

Domain 4: Environment