K30 case study: innovative treatment approach to myofascial neck pain

Marc Brodsky, MD
UCLA Center for East-West Medicine
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Patient presentation

- 24 yo female medical student with a one-year h/o neck pain that began during a time of intense stress during a visit with her parents
- Dyspepsia
- Constipation
- Dysmenorrhea
- Dry, red eyes
- Cold intolerance
- Insomnia
- Mechanistic (parts, objects, contents)
- Problems in isolation
- Analytical thinking
- Treatment aims to block, stimulate, or replace

- Holistic (whole, relationships, patterns)
- Problems of the system
- Principles of organization
- Treatment emphasizes self-healing
How is CAM classified?

NCCAM groups CAM practices into four domains, recognizing there can be some overlap. In addition, NCCAM studies CAM whole medical systems, which cut across all domains.

http://nccam.nih.gov/
Integrative Medicine

Healing oriented medicine that takes account of the whole person (body, mind and spirit) including all aspects of lifestyle. It emphasizes the therapeutic relationship and makes use of all appropriate therapies, both conventional and alternative.

Hands-on physical exam

- Locally tender point in taut band of muscle
- Characteristic radiation of pain with pressure
- Pressure can produce twitch response

Standard of care for myofascial pain

- Trigger point injection
- Physical therapy
- Medications (muscle relaxant, NSAID, botox)
- Lifestyle changes to address factors that contribute to trigger points

http://www.emedicine.com/pmr/topic84.htm
Wellness treatment plan

**Intensive Management**
Leverage available resources to optimize health status and coordination of care

**Care Management**
Enhance self-care skills; provide clinical management using care paths and protocols

**Self-care Support**
Routine care with decision support technology and programs to assist members in developing/ improving self-care skills
The World Health Organization defined "quality of life" in its constitution in 1948 to include physical, mental, and social well-being, and not just the absence of disease or illness.
SF-36: Physical health

Physical Health

- Physical function (10)
- Role – physical (4)
- Pain (2)
- General Health (5)
SF-36: Mental health

Mental Health

- Emotional Well-Being (5)
- Role-emotional (3)
- Energy/fatigue (4)
- Social function (2)
Integrative approach to patients with neck pain

- Pilot data from a cohort of 50 consecutive patients with neck pain recruited for 2000-2010 Neck Pain Task Force
- Compare change in health-related quality of life (HRQOL) at baseline and after 6 weeks of treatment
Change in SF-36 scores

Multi-item scales
## Statistical significance

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Research interest: is capsaicin an effective biologic treatment for myofascial pain?

- Capsaicin binds to a vanilloid type I receptor (VR1) on a trigeminal non-myelinated group C fiber
- Influx of sodium and calcium ions results in depolarization, which in turn opens voltage gated sodium channels (VGSC) and generates an action potential along the nerve fiber
- Transmitter substances including glutamate, Substance P (SP) und Calcitonin Gene Related Peptide (CGRP) transfers the signal to central neurons responsible for the perception of irritation and pain
Topical capsaicin and analgesia

- Diabetic and post-herpetic neuropathy
- Osteoarthritis
- Rheumatoid arthritis
- Post-mastectomy pain

What is a hydrogel

- Polymer chains that are water-insoluble
- Can contain over 99% water
- Natural or synthetic polymers
Capsaicin-containing hydrogel

- Improve the permeability and patient compliance of existing cream dosage forms
- Hydrogels have been investigated because of their controlled-release characterization and good tissue compatibility
FDA guidelines to evaluate in vitro and in vivo absorption

- Permeation of stratum corneum (SC) is rate limiting step
- Membrane to assess in vitro release of drug
- Dermato-pharmacokinetics to assess in vivo
Methods: in vitro skin permeation

- Determined by Franz diffusion cell
- Skin of rat on a receptor compartment with SC-side facing the donor compartment
- Donor compartment filled with test drug
In vitro permeation of capsaicin across rat skin

Capsaicin permeation across rat skin from study hydrogel is consistent with Dr. Fang’s previous studies.
Methods: skin erythema determination

- SC removed
- Mexemeter placed on treated skin surface
- Result of erythema was difference from control value at untreated site
## Safety analysis

<table>
<thead>
<tr>
<th>Skin condition</th>
<th>Value</th>
<th>Δ Value&lt;sup&gt;a&lt;/sup&gt;</th>
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<tr>
<td>a* (skin erythema)</td>
<td>-0.61±0.53</td>
<td>-1.28±2.13</td>
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<tr>
<td>Transepidermal water loss (g/m²/h)</td>
<td>13.19±2.42</td>
<td>1.23±2.47</td>
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</table>

<sup>a</sup> Δ value indicates the value of patch-treated skin area minus the non-treated skin area (control).
**Evaluation Question**
Does a topical capsaicin 500 mcg patch applied to 2 trigger points 12h on and 12h off each day for 1 month improve quality of life in patients with myofascial pain relative to a matched sample with placebo

**Standard**
Statistically significant ↑ in post-intervention scores on quality of life instrument (global as well as pain specific) and VAS relative to placebo
60 patients with chronic neck pain will be randomized into 2 groups of 30:

**Phase 1**
- PLACEBO
  - 30 patients will apply gel without capsaicin 12h on 12h off x 4 weeks
- TREATMENT
  - 30 patients will apply gel with capsaicin 12h on 12h off x 4 weeks

**Phase 2**
- PLACEBO
  - 30 patients will apply gel without capsaicin 12h on 12h off x 4 weeks
- TREATMENT
  - 30 patients will apply gel with capsaicin 12h on 12h off x 4 weeks

4-week wash out

McGill Pain Inventory, VAS, SF-36