Engineering Distinguished Lecture Series

Engineering for the Body: Reproducing body functions

Thursday, October 24, 2013

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Distinguished Lecture Series: Engineering for the Body: Reproducing body functions.
Thursday, October 24, 2013, 7:00-8:00
The Point Event and Conference Center at Walter Pyramid
California State University, Long Beach, California

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Counter-stimulation

He hit his thumb and then shook his hand and arm.
He hit his thumb
and then
shook his hand and arm
Pain + nothing else = Pure Pain

Pain + another sensation = Less pain

The other sensation = Counter-stimulation

Counter-stimulation = a Natural Body Function
Restless legs syndrome (RLS) is a brain disorder (as opposed to a leg disorder)

- Comes on when patients are drowsy or asleep
  - Is hard to describe; not really pain
  - Keeps people from falling asleep
  - Awakens people when they are asleep
    - Is like a phantom limb?
    - Is like an hallucinations or dream?
Restless legs syndrome (RLS) is a brain disorder (as opposed to a leg disorder)

• **Stand up, and it goes away**
  (but humans can’t sleep standing)

• **Standing up = Counter-stimulation**
? a man-made sensory stimulus = counter-stimulation of standing up?
“Bedroom in the Lab”
Counter-stimulation could be:

- Heat
- Cold
- Vibration
- Compression
- Transcutaneous Electrical Nerve Stimulation
- Light
- Sound
- Chemical – “Icy-Hot”
Sort for:

1) Stay in Bed
2) Easy to apply and return to sleep

Thrown out:
Chemical, TENS, Heat, Cold

Design Test matrix to evaluate patient response
Samples Tested

- High Frequency Vibration, 30-60 Hz
- Low Frequency Vibration, 0.5-10Hz
- Variable Light and Sound, Patient Controlled
- Fixed Light, No Control
- Pneumatic Sleeve, 0.01 - .1 Hz
- Vibration Cuff, 30-60 Hz
Results/Rankings

1- High Frequency Vibration
2- Low Frequency Vibration
3- Variable Sound
4- Variable Light
5- Pneumatic Sleeve, Fixed Light, Vibration Cuff
Improving sleep for patients with restless legs syndrome. Part II: meta-analysis of vibration therapy and drugs approved by the FDA for treatment of restless legs syndrome

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Background: Vibration therapy has been shown to improve sleep in patients with restless legs syndrome (RLS) to a greater extent than sham therapy. The current gold standard treatment for RLS is iron supplementation. However, the efficacy and safety of vibration therapy in comparison to other treatments is not well established. The aim of this study was to determine the efficacy and safety of vibration therapy in treating RLS.

Methods: A PubMed search was conducted to identify all clinical trials comparing vibration therapy to sham therapy in patients with RLS. The primary outcome measure was the change in sleep quality as measured by the Pittsburgh Sleep Quality Index (PSQI). A meta-analysis was performed to compare the effect sizes of vibration therapy to sham therapy.

Results: Ten clinical trials were identified, including a total of 345 patients with RLS. Vibration therapy was found to significantly improve sleep quality compared to sham therapy (standardized mean difference = 0.35, P < 0.05). There was no significant difference in adverse events between vibration therapy and sham therapy.

Conclusion: Vibration therapy is an effective and safe treatment for RLS. Further research is needed to determine the optimal parameters for vibration therapy.

Keywords: meta-analysis, restless legs syndrome, sleep, vibration therapy

Introduction

Restless legs syndrome (RLS) was first identified in 1868 and is characterized by uncomfortable or tingling sensations, which result in an overwhelming urge to move the legs. These urges are relieved in part or in whole by movement, such as walking, but may resume soon after activity ceases. RLS may also occur during the daytime and in the arms. Sleep-deprivation...
Better than shams
comparable to FDA-approved drugs

<table>
<thead>
<tr>
<th>Grouped by</th>
<th>Study name</th>
<th>Statistics for each study</th>
<th>Hedges's g and 95% CI</th>
</tr>
</thead>
<tbody>
<tr>
<td>Vibration</td>
<td>SMI-001</td>
<td>Hedges's g: -0.527, Lower limit: -0.983, Upper limit: -0.072, Z-Value: -2.268, p-Value: 0.023</td>
<td></td>
</tr>
<tr>
<td>Vibration</td>
<td>SMI-002</td>
<td>Hedges's g: -0.242, Lower limit: -0.701, Upper limit: 0.218, Z-Value: -1.031, p-Value: 0.302</td>
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<tr>
<td><strong>Vibration Fixed Effect Summary</strong></td>
<td></td>
<td>Hedges's g: -0.386, Lower limit: -0.709, Upper limit: -0.062, Z-Value: -2.336, p-Value: 0.019</td>
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<tr>
<td><strong>Drug Fixed Effect Summary</strong></td>
<td></td>
<td>Hedges's g: -0.436, Lower limit: -0.506, Upper limit: -0.365, Z-Value: -12.086, p-Value: 0.000</td>
<td></td>
</tr>
</tbody>
</table>

Gaba = gabapentin, enacarbil, Prami = pramipexole, Ropi = Ropinirole, Rotig = Rotigotine
Our FDA experience

4 years, 2 months, and 28 days to say to “NO”

Appeal  Reversal on 6/28/2013

Clock still ticking at 5 Years, 16 days