Use of Single Pulse TMS (sTMS) to treat migraine with medication overuse

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Background
- Many patients suffer disabling, frequent migraine without effective treatment as current pharmacological options are either contra-indicated, poorly tolerated or overused.
- Addressing the overuse of acute medicines is a challenging and crucial component of migraine treatment in clinical practice.
- The non-invasive, portable sTMS device is designed for patient use and received a CE mark in 2011 for the acute treatment of migraine.
- In a previously published, randomised, sham-controlled study, SpringTMS was shown to be effective for the acute treatment of migraine with aura 1.
- The safety of sTMS in clinical practice, including as an acute migraine treatment, is supported by biological, empirical, and clinical trial evidence. 2
- The National Institute for Clinical Excellence (NICE) approved TMS for acute and preventive treatment of migraine in the UK.
- A UK post market pilot programme with the SpringTMS device has shown efficacy and safety for patients with migraine 3.

Objectives
- To explore the utility of sTMS to treat migraine with acute medication overuse.
- To evaluate responses in an open outpatient setting.
- Assess impact on acute medication use, pain, migraine days, attack duration and headache disability (HIT-6) over an extended period (minimum three months).

Methods
- Neurologists selected patients in clinic and advised a reduction of acute medicines (n = 28) in conjunction with the sTMS device.
- Medications being overused were Triptan only (n = 7), Triptan plus OTC (n = 19) and OTC only (n = 2).
- Patients received the device to use for a minimum period of three months with the option to treat for an additional 3 months.
- Headache nurses provided treatment instructions and collected baseline and outcome data through telephone surveys at Baseline, 6- and 12-week time points.
- Patients were instructed to treat with sTMS twice daily and acutely at attack onset, using the sTMS Medical Advisory Board (TMS-MAB) guidelines.
- At six months, acute medicine use and HIT-6 scores were sought.

Patient Characteristics

<table>
<thead>
<tr>
<th>Migraine Features</th>
<th># of Patients</th>
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<tbody>
<tr>
<td>Migraine with aura</td>
<td>12</td>
</tr>
<tr>
<td>Migraine without aura</td>
<td>16</td>
</tr>
<tr>
<td><strong>Of these:</strong></td>
<td></td>
</tr>
<tr>
<td>Female</td>
<td>22</td>
</tr>
<tr>
<td>Male</td>
<td>6</td>
</tr>
<tr>
<td><strong>Average Age</strong></td>
<td>48 (±11)</td>
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Results
- 28 patients used the device for a minimum of three months and completed surveys. Of these:
  - 24 patients (86%) reported a reduction in the number of days of medications use
  - 21 (75%) reported a reduction or alleviation of pain
  - A reduction in the number of headache days was reported by 19 patients (68%) with 54% also having a shorter duration (n = 15)
  - Headache disability scores (HIT-6) were improved in 75% (n = 21)
  - The treatment was well tolerated with no adverse events reported
  - Five patients discontinued treatment because of inadequate benefit or inconvenience
- At 6 months, 16 of the 19 patients (84%) who provided data on acute medication use, maintained reduced acute medication days and 19 patients (68%) provided HIT-6 scores; these were comparable to their 12-week scores.

Conclusion
- sTMS may be an effective bridge treatment for migraine patients with medication overuse.
- The majority of patients reduced acute treatments and reported efficacy for migraine symptoms.
- SpringTMS is a new and effective NICE UK-approved, non-drug treatment option for patients with migraine.
- These results are consistent with this CE marked device being safe to use in outpatient practice.
- The data suggests the device, in responders, continues to provide reliable, reproducible effects on migraine and acute medication use over time.

3 NICE. www.nice.org.uk/IPG477