Update of the UK post market pilot programme with single pulse transcranial magnetic stimulation (sTMS) for acute treatment of migraine

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Background

• Some patients suffer disabling, frequent migraine without effective treatment as current pharmacological options are either contra-indicated, poorly tolerated or overused.
• The non-invasive, portable, sTMS device is designed for use by patients at home, for self-management of migraine attacks.
• In a previously published, randomised, sham-controlled study, SpringTMS was shown to be effective for the acute treatment of migraine with aura.
• The safety of sTMS in clinical practice, including as an acute migraine treatment, is supported by biological, empirical, and clinical trial evidence.
• A post market pilot programme with the SpringTMS device was initiated for patients with migraine.
• The National Institute for Clinical Excellence (NICE) approved TMS for acute and preventive treatment of migraine in the UK.

Objectives

• Evaluate responses in an open outpatient setting
• Assess impact on pain, associated migraine symptoms and acute medication use over an extended period (minimum three months)
• Understand patient support and educational needs
• Assist patients in establishing optimal treatment schemes for their migraine patterns
• Review options for sTMS within the UK headache care pathway

Methods

Clinicians selected patients and prescribed the device. Patients received the device to use for a minimum period of three months. A specialist nurse had first contact with the patient to discuss treatment and use. Telephone reviews were conducted at 4 to 6-weekly intervals to support and monitor the patients’ treatment and progress. Survey data was collected at the 6 and 12-week time points over the treatment period.

Patient Characteristics

<table>
<thead>
<tr>
<th>Migraine Features</th>
<th># of Patients</th>
<th># of Attacks Treated</th>
</tr>
</thead>
<tbody>
<tr>
<td>Migraine with aura</td>
<td>61</td>
<td>3072</td>
</tr>
<tr>
<td>Migraine without aura</td>
<td>61</td>
<td>2253</td>
</tr>
<tr>
<td>Of these:</td>
<td></td>
<td></td>
</tr>
<tr>
<td>Episodic</td>
<td>44</td>
<td>1704</td>
</tr>
<tr>
<td>Chronic</td>
<td>78</td>
<td>3621</td>
</tr>
</tbody>
</table>

This programme was sponsored by eNeura Inc.

Results

• 122 (35%) patients have been using the device for a minimum of three months and completed surveys. A total of 351 patients have been prescribed stMS.
• 88 patients (72%) reported a reduction or alleviation of pain.
• Associated symptoms (nausea 64%; photophobia 84%; phonophobia 89%) improved or did not develop.
• A reduction in the number of headache days was reported by 76 (62%).
• 71 (58%) reported a reduction in the duration of migraine symptoms per attack.
• 101 (83%) were also using an acute medication at the time of prescription. Of these, 69 (68%) reported a reduction in the number of days of medications use.
• The treatment was well tolerated with no serious adverse events reported.
• For those patients who reported clinical response, these were reproducible throughout the 3 month period and beyond.

Conclusion

• SpringTMS is a new and effective NICE UK-approved, acute and adjunctive, 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 over time.

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3 NICE www.nice.org.uk/IPG477