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[3] (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[4] .

Objectives

- To explore the utility of sTMS to treat migraine with acute medication overuse.
- 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).

Patient Characteristics

Migraine Features	# of Patients
Migraine with aura	12
Migraine without aura	16
Of these:	
Female	22
Male	6
Average Age	48 (± 11)

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.

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.

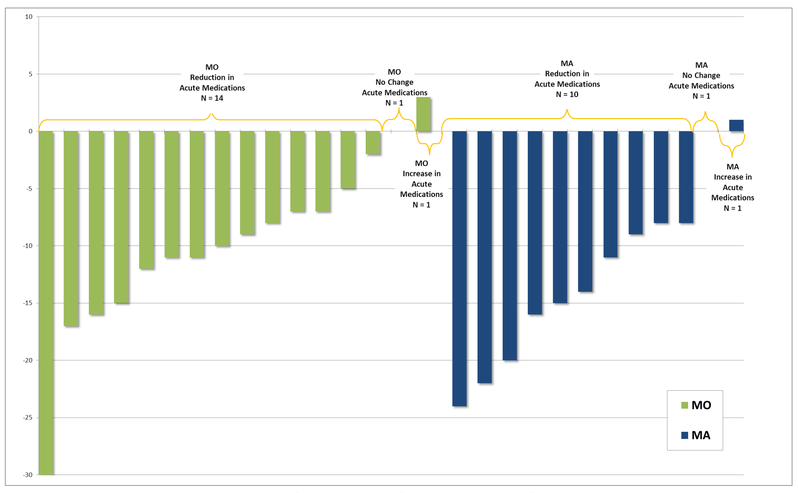

Figure 1: Reduction of Acute Medicine Days

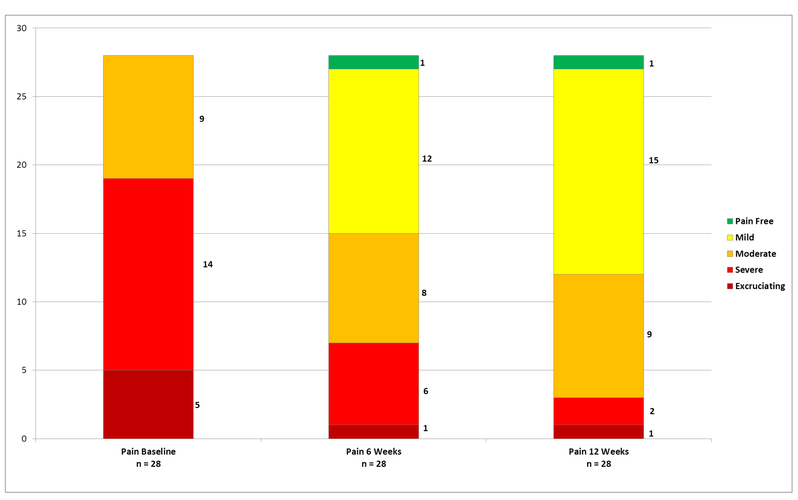

Figure 2: Effect of sTMS on Pain Severity

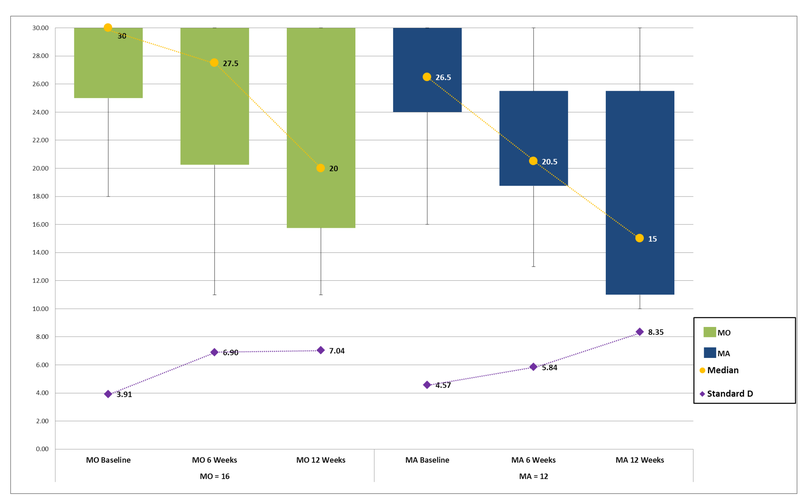

Figure 3: Reduction of Migraine Days

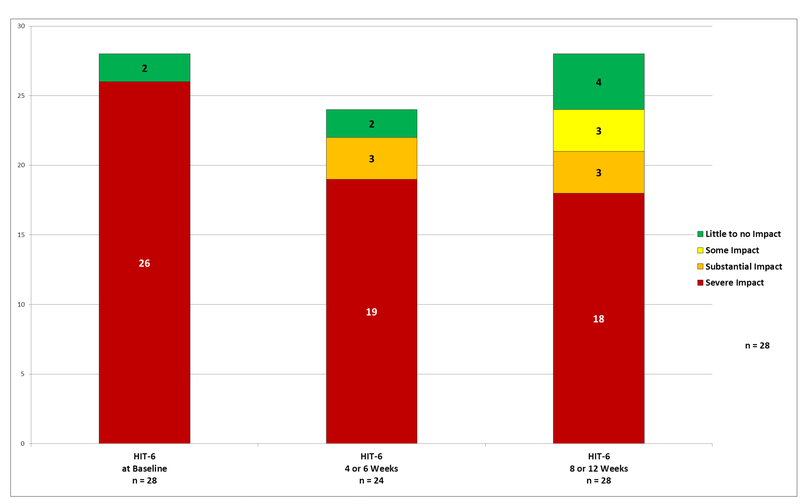

Figure 4: Effect on HIT-6 Score

SPRINGTMS

eNeura's Medical Advisory Board
Suggested Treatment Plan for the Acute Treatment of Migraine Using SpringTMS**

The following treatment plan is suggested to derive more meaningful results to assess and advise patients using the SpringTMS. During the pilot program it is suggested that patient selection emphasize episodic migraine with and without aura.

It is important to:

- **Initiate treatment as early as possible** when patient first experiences symptoms of migraine, including pain and/or aura symptoms.
- **Fill-out the headache diary** immediately after treatment or at any time after the migraine attack subsides.
- **Increase the number of pulses delivered** during an attack using the following systematic method as needed to improve pain and symptom relief.

To Begin:

- Encourage the patient to deliver 2 sequential pulses as early as possible at the beginning of the migraine attack.
- Continue with 2 pulses every 15 minutes for 1-2 hours or until pain and symptoms resolve.
- Encourage patients to withhold using rescue medication for the first hour or two if possible.

Evaluate after the first month (3-4 attacks) - if needed increase the number of pulses delivered

- Encourage the patient to deliver 3 sequential pulses as early as possible at the beginning of the migraine attack.
- Continue with 3 pulses every 15 minutes for 1-2 hours or until pain and symptoms resolve.

Evaluate again after the second month (3-4 attacks) - if needed increase the number of pulses delivered

- Encourage the patient to deliver 4 sequential pulses as early as possible at the beginning of the migraine attack.
- Continue with 4 pulses every 15 minutes for 1-2 hours or until pain and symptoms resolve.

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Figure 5:TMS-MAB Guidelines

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.**

1 Lipton R.B., Dodick D.W., Silberstein S.D et al. Single-pulse transcranial magnetic stimulation for acute treatment of migraine with aura: randomized, double-blind, parallel-group, sham controlled trial. The Lancet Neurology 2010;9:373-380.
2 Dodick D.W, Schembri C.T., Helmuth M et al. Transcranial magnetic stimulation for migraine: a safety review. Headache 2010; 50:1153-1163.
3 NICE www.nice.org.uk/IPG477
4 Bhola R., Kinsella E., Ahmed F. and Goadsby P. ; UK Post market pilot programme with single pulse transcranial magnetic stimulation (sTMS) for acute treatment of migraine. Journal of Headache and Pain. 2014;15(Suppl 1):M2.