0	1	2	3	4	5	6	7 ✓	8	9	10

No progress Excellent progress

SIGNED MPridgeon DATE: 22/04/2024

(Print name) Michael Pridgeon

Pain Relief Foundation Research Grant

'Reversal of EEG Theta band rhythm as an objective measure of efficacy of spinal cord stimulation in chronic neuropathic pain – a pilot study'

Report summary:

The study over the last financial year has consisted of a scoping review to benchmark current literature evidence and data collection.

1. Scoping review

This scoping review aims to explore the role of two neurophysiological biomarkers QEEG and SSEP, in the assessment of chronic neuropathic back pain with spinal cord stimulation (SCS) and registered with the open science framework (OSF) as a generalized systematic review (14th January 2024).

The primary aim of the review was to synthesize evidence of EEG spectral power changes in chronic neuropathic pain. Synthesize evidence of SSEP measures in chronic neuropathic pain. Combine and compare evidence for changes in EEG and SSEP measures with spinal cord stimulation. Secondary aims included an exploration in the role of sleep and medication on these measures in chronic neuropathic pain.

Hypothesis: An increase in QEEG theta power and augmentation of SSEP amplitudes can be used as biomarkers of chronic neuropathic pain and that theta QEEG power and SSEP amplitudes are reduced by effective spinal cord stimulation using either low (tonic), high, or burst stimulation.

A PICO search strategy was used to search Pubmed (Medline), SCOPUS and Web of science. All search results were imported into Covidence to perform de-duplication and processing of the subsequent stages. Titles and abstracts were initially screened for eligibility according to the inclusion and exclusion criteria. Included abstracts were full text screened for eligibility. Relevant qualitative and quantitative data were extracted from the papers and synthesized.

- Search results = 1468 papers (web of science = 1036, Pubmed = 416 and Scopus = 16)
- Duplicates removed = 71
- Studies screened (abstract and title) = 1397
    - Included = 60
    - Excluded = 1337
- Full screen
    - Included = 25
    - Excluded = 35

- Screened for EEG / SSEP measures with SCS
    - EEG papers = 14
    - SSEP papers = 8
    - Excluded = 3

The studies were either case series or case studies, quality was assessed using a case series quality appraisal check list with scores out of 20 (mean = 9/20, range 3-13/20, variance = 8.83, standard deviation = 2.97).

EEG studies showed the greatest heterogeneity, in technical parameters with agreement on analysis methodology. All the papers used tonic SCS. Study sizes varied for EEG studies ranged from 1-21 subjects (mean = 9) and SSEP primary studies ranged from 1-24 (mean = 11). All studies were prospective.

Synthesis

Effect size: Percentage pain reduction after SCS (tonic)

- EEG= 48.3% (n=1)
- SSEP = 67.7% (n=4)
- Combined = 63.5%

The other studies I could not calculate percentage pain relief.

Effect size: SSEP percentage P37/P40 amplitude decrease.

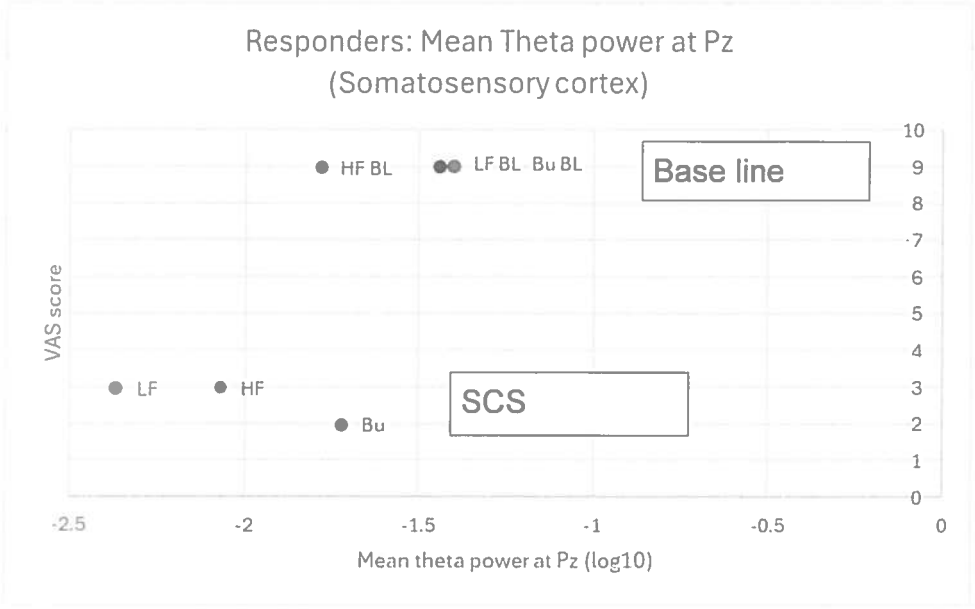
- Combined = 36.6% (n= 4)

The other studies I could not calculate percentage amplitude drop.

2. Data collection

   Study recruitment despite a slow start is now proceeding at a steady pace on target, I have currently recruited 24 patients, loosing three at baseline studies due to travelling distance for return trials, there is also an additional patient mid-trial at the time of writing this report (n =21). There have been no deviations from the study protocol and no reported adverse events.

Analysis to date: EEG data using VAS (n=20), graph shows mean scores



Effect size: Percentage pain reduction after SCS:

- HF SCS responders = 65%
- LF SCS responders = 68%
- Burst SCS responders = 72%
- Combined = 68.3%

Percentage pain reduction after tonic SCS is in keeping with the literature. HF and Burst SCS shows similar results with burst showing the greatest pain reduction. I have not tested statistical significance currently.

Summary of next stages

- Complete recruitment (phase 1)
- Phase 2: Continue EEG data analysis and test for statistical significance.
- Analyse SSEP data
- Analyse all data using Pain detect, Oswestry disability index.

<u>Summary</u>

The project is on track for completion, phase 1 is nearly completed, I already have enough participants to match the samples sizes of the upper range of primary studies in the current literature (power, n=36). Phase 2 – analysis has been started with interesting EEG preliminary results in keeping with the literature.

MPridgeon

Michael Pridgeon
Principal investigator