REDUCING MAJOR DEPRESSIVE DISORDER SYMPTOMS WITH TRANSCRANIAL DIRECT CURRENT STIMULATION TREATMENT

A REAL-WORLD STUDY

THE LARGEST DATASET HITHERTO ON THE EFFECTS OF TDCS FOR TREATING MDD IN REAL-WORLD CLINICAL PRACTICE

STUDY HIGHLIGHTS

Data from 410 patients treated with Sooma tDCS™ Depression Therapy as a part of routine clinical practice was successfully gathered and analysed.

After completing the treatment, 55% of the patients achieved complete clinical response. Remission was achieved by about 20%.

This real-world study shows good tolerability and reduced depressive symptoms in patients with MDD after treatment with Sooma tDCS™ Depression Therapy.

Transcranial direct current stimulation (tDCS) relieves the symptoms of major depressive disorder (MDD) by modulating cortical excitability with a weak current.

tDCS delivers a constant current that induces changes in neuronal excitability in a polarity-dependent manner (Tortella et al. 2015). In Sooma Depression Therapy, the positive anodal stimulation is used to increase neuronal excitability at the left dorsolateral prefrontal cortex (DLPFC), which is found to be hypoactive in depressed patients (Fitzgerald et al. 2006, Grimm et al. 2008).

The flow of current between the positive and the negative electrode influences the neuronal activity in the prefrontal cortex (Tortella et al. 2015) and leads to relieving symptoms in depressed patients (Razza et al. 2010).

Based on evidence from clinical trials and meta-analyses, tDCS is considered an effective and well-tolerated treatment for MDD with an A level of evidence (Fregni et al. 2021).

tDCS is a non-invasive neuromodulation method that can be administered as a monotherapy, or as an adjunct therapy to pharmacological or psychosocial treatments (Brunoni et al. 2013, Segrave et al. 2014, National Institute for Health and Care Excellence 2015a, National Institute for Health and Care Excellence 2015b, Brunoni et al. 2011, Mutz et al. 2018, Brunoni et al. 2016).

More importantly, certain tDCS therapies–like Sooma Therapy, can be administered at home by the patient after being prescribed by a physician, thus alleviating the workload of clinics and hospitals.

SOOMA TDCS™THERAPY

CLINICAL USE STUDY DATA

PATIENTS AND METHODS

Sooma Depression Therapy is conducted using a portable device and proprietary Sooma accessories (Figure 1). This maximizes patient comfort while enabling reproducible electrode placement to targeted locations on the scalp.

The real-life effectiveness and tolerability of Sooma tDCS™ Depression Therapy was evaluated in a cohort of 462 MDD patients from seven countries, who were treated with tDCS as a part of routine clinical practice. Treatment data of a total of 410 (89%) of those patients were included into the analysis as a full report was received on them after successfully completing the treatment course. All patients were treated according to the following stimulation protocol: a 2-mA current

FIGURE 1

for 30 minutes, delivered through electrodes in a F3-F4 montage, five time a week for a total of 2-3 weeks, followed by a maintenance treatment according to the patients' needs.

Baseline (pre-treatment) and end-point (post-treatment) depression depressive symptoms were scored according to one of the following validated depression scales: HDRS-17, HDRS-21, HDRS-24, BDI-21, MADRS, MDI, or GDS. Study outcomes were clinical response (defined as >50% reduction from the baseline depression score), and remission (defined by the grading guideline of each depression scale).

At baseline, approximately half of the patients had moderate depression (52%), whereas 38% had severe, and 10% mild depression (Table 1). Sooma tDCS™ was used as a monotherapy with 107 patients and as an add-on to stable medication for the rest (n = 303). The simultaneous treatments were not modified during Sooma Depression Therapy.

Patients	n (%)
Total number of patients	462 (100)
Completed treatment	410 (89)
Median age in yers (±SD)	41 (13)
Females	237 (58)
Males	173 (42)
Pre-treatment severity	**n (%)**
Severe	157 (38)
Moderate	213 (52)
Mild	40 (10)
Concomitant medication	**n (%)**
Monotherapy	107 (26)
Medication use (of which:)	303 (74)
Antidepressants	290 (96)
Antipsychotics	76 (25)
Benzodiazepine	33 (11)
Mood stabilizers	7 (2)
Treatment protocol	**n (±SD)**
Mean follow-up time (weeks)	23 (8)
Mean treatment sessions / patient	16 (4)

Table 1. Patient demographics and treatment characteristics.

EFFECTIVENESS

Most patients (97%) experienced an improvement in their depression score after the treatment with Sooma tDCS™ Depression Therapy. 55% (n = 225) of the patients achieved clinical response. Impor-

Patients

n= 410

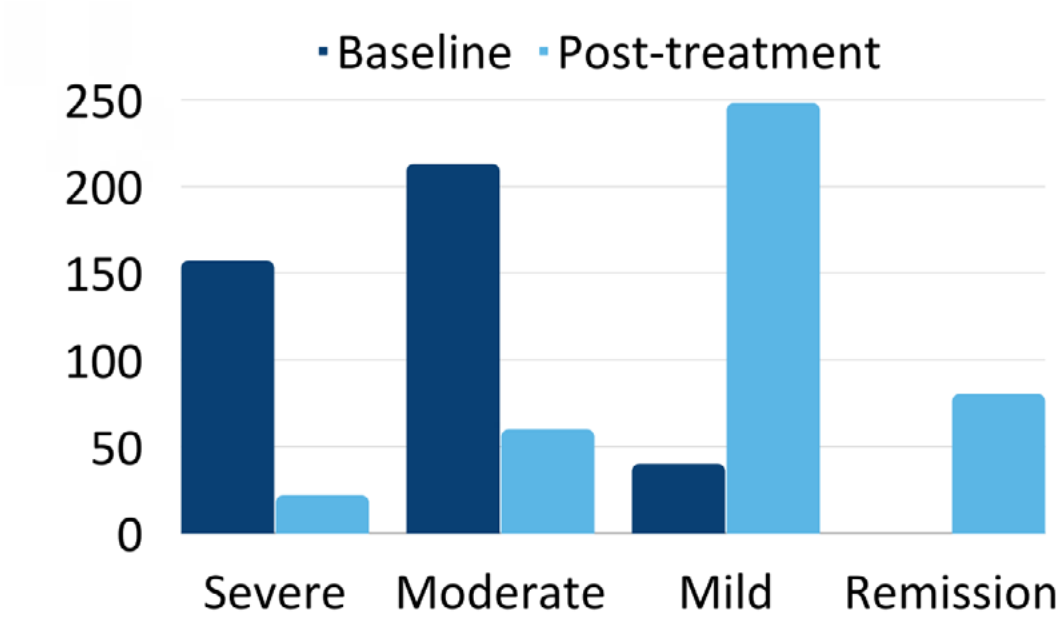
42% 58%

Treatment outcomes

55%
Response rate

20%
Remission

Depression severity



Adverse events

0%
Serious adverse events

44%
Itching

25%
Headache

18%
Skin redness

sooma

tantly, post-treatment, about 20% (n = 80) of the patients had achieved remission, and majority of the patients were now with mild depression 248 patients (61%), while only 60 (15%) had moderate, and only 22 (5%) had severe depression.

At least half of the patients achieved clinical response in all severity classes and in patients with and without concomitant use of psychotropics. Monotherapy patients had a higher response (68%) and remission rates (35%) compared to patients with concomitant use of medication (50% and 14%, respectively).

SAFETY

No serious adverse effects were reported during the treatment. The majority of reported adverse events were mild and transient reactions to the treatment.

The most common adverse effects observed were skin itching under the electrodes during the stimulation (44%), headache (close to 25%), and skin redness (almost 18%). Hypomania was observed in two patients (0.5%).

CONCLUSIONS

This real-world study shows good tolerability and reduced depressive symptoms in patients with MDD after tDCS treatment with Sooma devices.

This study demonstrated that, after tDCS treatment, a majority of patients (>90%) showed an improvement of their depression score, and more than half achieved clinical response after the treatment course. Furthermore, after the treatment the majority of patients were left with mild depression (61%) if not in remission (20%). This should correlate to an improved functionality and quality of life and reduced healthcare burden.

Concomitant use of psychotropics was found negatively associated with achieving both a clinical response and remission, whereas having a more severe disease was negatively associated with remission only. These results suggest that patients with milder depression severity and no concomitant use of psychotropics might obtain greatest benefit from tDCS therapies.

The results suggest that tDCS is a well-suited treatment alternative for MDD, either as a stand-alone treatment or in combination with antidepressant medication.

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SOOMA OY

Sooma Oy is a Finnish medical device company developing accessible therapy solutions for routine care.

Sooma tDCS medical devices are manufactured in Finland in accordance with the international ISO 13485 quality management system for medical devices.

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