White paper

Transcranial direct current stimulation (tDCS): an overview of clinical and real-world evidence in major depressive disorder

Summary

- Non-invasive Sooma tDCS™ Depression Therapy relieves depression by modulating hypoactive areas of the brain with a weak current
- Real-world clinical effectiveness of Sooma tDCS™ was assessed, as a monotherapy or as an add-on therapy, in 227 patients with major depressive disorder (MDD)
- Treatment response was achieved in 59% of patients, and 18% of patients were in complete clinical remission at follow-up, a mean time of 21 days
- Sooma tDCS™ Depression Therapy was well tolerated: the majority of adverse events were mild and transient, and there were no serious adverse events

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.[1] The positive anodal stimulation increases neuronal excitability at the left dorsolateral prefrontal cortex (DLPFC), which is found to be hypoactive in depressed patients.[2,3] The flow of current from the positive to the negative electrode balances the activity in the prefrontal cortex[1], relieving symptoms in depressed patients.[4]

tDCS can be administered as a monotherapy, or as an adjunct treatment to enhance the effect of pharmaceutical or psychological therapy.[5,6] The efficacy and safety of tDCS has been shown in randomized controlled studies, either as a monotherapy or as an adjunct therapy to pharmaceutical or psychosocial treatments.[5,7,8,9,10]

A meta-analysis of six randomized clinical trials (RCTs) with a total of 289 patients demonstrated the superiority of active tDCS to sham tDCS, with significantly higher response (33.3% vs. 19%, respectively) and remission rates (23.1% vs. 12.7%, respectively).[10] A mean response duration of 11.7 weeks was demonstrated in an open-label follow-up study of 42 patients who were responders in the initial study phase and continued to receive treatment.[11]

Sooma tDCS™ session:

2 mA direct current for 30 min

Acute treatment:
1 session per day,
5 days a week
for 2 to 3 weeks

Maintenance treatment:
1 session per week up to
6 months or as required

Figure 1. Sooma tDCS™ consists of a light-weight, battery-powered stimulator, electrodes with conductive medium, and a headcap with fixed electrode positions.

In a recent 10-week randomized double-blind placebo-controlled trial comparing tDCS with escitalopram on 245 patients, both tDCS and escitalopram were superior to placebo but non-inferiority to escitalopram was not shown.[12]

tDCS has also been studied in patients with bipolar depression. In a recent randomized, double-blind trial on 59 bipolar patients, significantly higher cumulative response rates were observed for patients receiving active tDCS compared to patients receiving sham treatment (67.6% vs. 30.4%).[13]

Current research evidence supports the use of tDCS in non-treatment-resistant depressive patients.[14,15] The National Institute for Health and Care Excellence (NICE) and the Canadian Network for Mood and Anxiety Disorders (CANMAT) have published detailed treatment guidelines of the use of tDCS in MDD.[7,8,16]

Real-world use of Sooma tDCS™

Patients and Methods

Sooma Depression Therapy is conducted using a portable device and a proprietary Sooma head cap (Figure 1). This maximises 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 227 MDD patients collected from ten primary and secondary care clinics worldwide. All patients were treated according to the standard Sooma tDCS™ stimulation protocol: a 2-mA current for 30 minutes every weekday for a total of 3 weeks, followed by optional maintenance treatment. Clinicians were allowed to adjust the number of treatment sessions according to the patients' needs.

Baseline (pre-treatment) and end-point (post-treatment) depression was scored by the treating nurse or psychotherapist according to their preferred depression scale: 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), remission (defined by the grading guideline of each depression scale), and the change in depression score from baseline to the end of treatment.

The majority of patients were severely (53%) or moderately (40%) depressed at baseline (Table 1). Sooma tDCS™ was used as a monotherapy in 27% of the cases and as an add-on therapy in 73% of the cases. 95% of the sessions were administered in outpatient setting. Altogether, 191 (84%) of the patients completed the treatment.

Table 1. Patient demographics and treatment characteristics.

Subjects	n (%)
Total number of patients	227 (100)
Patients with depression score available	221 (97)
Completed treatment	191 (84)
Mean age in years ± SD (range)	39 ± 13 (17–80)
Gender	n (%)
Female	105 (55)
Male	86 (45)
Pre-treatment severity	**n (%)**
Mild	13 (7)
Moderate	76 (40)
Severe	102 (53)
Simultaneous treatment	**n (%)**
Monotherapy	51 (27)
Add-on therapy*	140 (73)
Psychotherapy	5 (3)
Antidepressant	127 (66)
Antipsychotic	41 (21)
Benzodiazepine	19 (10)
Sooma tDCS™ Depression Therapy	
Total number of treatment sessions	2,879
Mean number of treatment sessions / person	15 ± 4 (6–25)
Treatment location	n (%)
Outpatient care	2,735 (95)
At home	144 (5)
Duration of follow-up in days ± SD (range)	21 ± 6 (11–35)

* Includes pharmacological treatment and psychotherapy
SD, standard deviation

Effectiveness

The majority of patients experienced a marked improvement as a result of Sooma tDCS™ Depression Therapy. Altogether, 113 patients (59%) achieved clinical response. A total of 34 patients (18%) achieved complete clinical remission, whereas 117 patients (61%) had mild, 25 (13%) had moderate, and 15 (8%) had severe depression at the end of the treatment period.

Almost all study subjects (94%) experienced an overall decrease in the depression score, the mean improvement being 49% ± 24%. Patients with no concurrent therapy had a higher response rate (76%) compared to patients receiving treatment as an add-on therapy (55%).

Safety

There were no serious adverse events in the cohort during the 2,879 treatment sessions. The majority of reported adverse events were mild and transient reactions to the treatment.

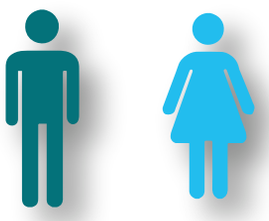
The most common adverse events were itching (58% of patients), headache (27%), skin redness at electrode sites (15%) and a burning sensation (13%). Two patients (1%) experienced a single episode of hypomania that did not require pharmaceutical intervention.

Real-world evidence of Sooma tDCS™ Depression Therapy

PATIENT COHORT

Patients

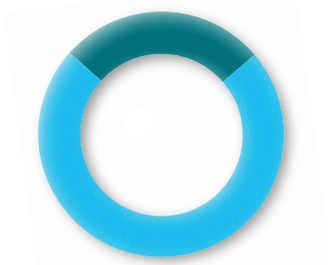
n=191



45% 55%

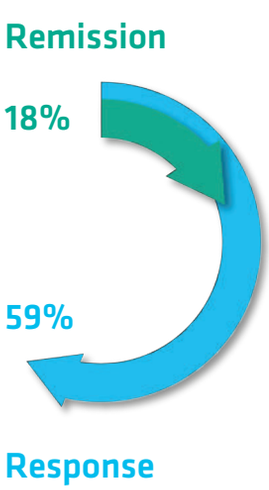
Severity of depression

Treatment

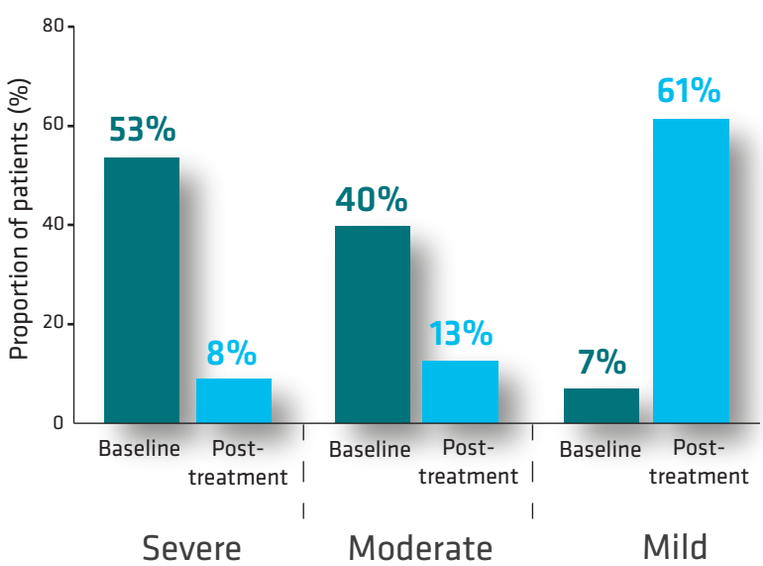


EFFECTIVENESS

Treatment outcomes



Change in depression severity



SAFETY

Most common adverse events

58% Itching

27% Headache

15% Skin redness at electrode sites

13% A burning sensation

Serious adverse events

0%

Conclusions

Based on evidence from clinical trials and meta-analyses, tDCS is an effective and well-tolerated treatment for MDD.[4,5,6,9,10,11] It is also important to evaluate effectiveness and safety of tDCS in real-world clinical practice.

In this real-world cohort of 227 patients, almost all patients treated with Sooma tDCS™ experienced an overall decrease in the depression score and the proportion of patients with severe depression decreased from 53% to 8%.

There were no serious adverse events and the majority of the reported adverse events were mild and transient. The treatment response was fast: the majority of patients achieved treatment response within the mean follow-up period of 21 days.

Sooma tDCS™ is an easy-to-use and cost-effective treatment option for patients with MDD. The treatment session can be administered by a trained nurse in a clinic, or by the patient at home. The treatment is easy to combine with pharmacological treatment, psychotherapy or group therapy, and the patient is free to engage in normal activities during the session.

The proportion of patients with severe depression decreased from 53% to 8% following Sooma tDCS™ Depression Therapy

Training on the use of Sooma tDCS™ is provided to health care professionals by Sooma Oy on request.

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About Sooma

Sooma is a Finnish manufacturer of innovative neuromodulation technologies. Sooma tDCS™ is a CE-marked, TGA and Health Canada approved medical device. Sooma Oy holds ISO13485 and ISO9001 certificates.

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