RESEARCH PAPER

Cathodal Pre-Supplementary Motor Area Transcranial Direct Current Stimulation as an Add-on Treatment in Treatment-Resistant Obsessive-Compulsive Disorder: A Case Series of 17 Patients

Running title: Add-on pre-SMA tDCS in resistant OCD: a case series

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Abstract

Background: Around one-third of people with obsessive-compulsive disorder (OCD) do not respond adequately to serotonin reuptake inhibitors (SRIs) and exposure and response prevention (ERP), which is often unavailable. Transcranial direct current stimulation (tDCS) over the pre-supplementary motor area (pre-SMA) is a simple, portable and inexpensive neuromodulation approach that has been tested as an add-on treatment, but results are variable and data from routine clinical settings are limited.

Case series presentation: We describe 17 consecutive adults (mean age 38.7 years; 70.6% male) with ICD-10 OCD, Y-BOCS ≥ 16 and at least two prior inadequate treatment trials with an SRI and/or ERP, who chose add-on tDCS at a tertiary-care psychiatry unit in India between November 2023 and May 2024. All were on stable psychotropic medication. Each received 10 sessions of 2 mA tDCS for 20 minutes, with the cathode over the pre-SMA (Fz) and the anode over the right occipital region (O2). Y-BOCS, the 17-item Hamilton Depression Rating Scale (HAM-D-17) and the Clinical Global Impression (CGI) scale were assessed before and at the end of treatment, and adverse effects were recorded with a structured checklist.

Outcomes: Mean Y-BOCS fell from 26.65 ± 6.05 to 22.41 ± 6.89 (mean percentage reduction 16.7%; $p < 0.001$) and mean HAM-D-17 from 11.58 ± 5.90 to 8.11 ± 4.79 (29.6%; $p < 0.001$). Two patients (11.8%) had a ≥ 35% Y-BOCS reduction (response), one (5.9%) a 25–34% reduction (partial response), and 14 (82.4%) a reduction below 25%. Mean CGI-Improvement was 2.88 ± 0.99. Adverse effects were mild and transient: headache in 5 patients (29.4%), and fatigue and nervousness in one each. There were no serious adverse events and no dropouts.

Conclusion: In this uncontrolled series, a 10-session course of add-on pre-SMA tDCS was well tolerated and followed by a modest average improvement in obsessive-compulsive and depressive symptoms, with a minority reaching response. Sham-controlled studies with longer courses and follow-up are needed.

Keywords: obsessive-compulsive disorder; transcranial direct current stimulation; pre-supplementary motor area; treatment-resistant; add-on treatment; case series

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Introduction

Obsessive-compulsive disorder affects an estimated 2–3% of people over the lifetime and causes chronic functional disability [1]. SRIs are the usual first-line drug treatment in India, while ERP, the most effective psychotherapy, is often unavailable because of cost and a shortage of trained therapists [2]. About one-third of patients do not respond to an SRI alone, and benefit can take two to three months to appear in those who do [3]. Antipsychotic augmentation benefits only a minority and has considerable side effects [4]. Given the persistent course of the illness and its impact on quality of life, additional treatment options are needed [5,6].

OCD is thought to involve dysfunction of cortico-striato-thalamo-cortical circuits, in which reduced inhibitory control of the basal ganglia by the pre-SMA may contribute to symptom expression. tDCS delivers a weak constant current through scalp electrodes to modulate cortical excitability, and is simple, portable, inexpensive and generally well accepted [7–9]. Pre-SMA-targeted tDCS, including cathodal montages, has been examined in randomised and open-label studies of treatment-resistant OCD, with mixed results [10–14].

We report a case series of 17 patients with treatment-resistant OCD who received a 10-session course of add-on cathodal pre-SMA tDCS, describing their clinical features, symptom trajectories and tolerability. These patients form the tDCS arm of a larger, preference-based cohort that also included a

group treated with intravenous ketamine; the full cohort is reported separately [15].

Methods

Design, setting and reporting

This is a prospective, open-label, uncontrolled case series of consecutive patients who chose tDCS, treated from November 2023 to May 2024 in the Department of Psychiatry, Sardar Patel Medical College and Associated Group of PBM Hospitals, Bikaner, Rajasthan, India. Patients were recruited from outpatient and inpatient services. The report is organised with reference to the CARE guideline for case reports and series.

Patients

Of 54 patients with a primary ICD-10 diagnosis of OCD screened for the parent cohort, 39 were enrolled after exclusions; all patients were informed of both available add-on options (tDCS or intravenous ketamine) and chose their preferred treatment. Seventeen chose tDCS and are described here.

Inclusion criteria were age 18–65 years, either sex; Y-BOCS ≥ 16; and treatment resistance, defined as at least two adequate prior trials of an SRI and/or ERP-based CBT [16]; and stable concomitant psychotropic medication for at least one month before and throughout the study. Exclusion criteria were comorbid bipolar disorder or psychotic disorder, active suicidal ideation, current non-nicotine substance use disorder, unstable medical or neurological illness, and pregnancy or breastfeeding.

Intervention

A constant direct current of 2 mA was delivered for 20 minutes per session for 10 sessions using a battery-operated stimulator (STARSTIM) with 25 cm^2 sponge electrodes. The cathode was placed over the pre-SMA (Fz) and the anode over the right occipital region (O2), according to the international 10–20 EEG system. [Authors to add: session schedule (sessions per day/week), current ramp-up/ramp-down, and electrode preparation.] Psychotropic medication doses were not changed during the study.

Assessments

OCD severity was rated with the Yale-Brown Obsessive Compulsive Scale (Y-BOCS) [17] and depressive symptoms with the HAM-D-17 [18], at baseline and at the end of the treatment course. Global severity and improvement were rated with the CGI-Severity and CGI-Improvement scales [19]. Response was defined as a Y-BOCS reduction of ≥ 35% and partial response as a reduction of 25–34%; the proportion with a reduction of ≥ 25% is also reported. Adverse effects were recorded on a structured checklist.

Analysis

This is a descriptive series. Continuous variables are given as mean ± SD or median [interquartile range] and categorical variables as n (%). Change from baseline to end of treatment was examined with paired t-tests; p-values are descriptive, as there was no control group. The relationship between percentage reductions in Y-BOCS and HAM-D-17 was examined with Pearson correlation. A two-sided $p < 0.05$ was taken as significant. Analyses used SPSS 24.0 and Epi Info 7.2.6.0.

Results

Characteristics of the series

All 17 patients completed the 10 sessions and both assessments; none was lost to follow-up. Baseline characteristics are shown in Table 1. Most patients were men in their late thirties with onset in early adulthood and a median illness duration of 10 years. Washing/cleaning compulsions were the most frequent predominant symptom type (10 patients, 58.8%). Fourteen patients (82.4%) had a comorbid psychiatric disorder, most commonly depression or anxiety. Individual patient-level details are given in Table 5.

Table 1. Baseline characteristics (n = 17)

Characteristic	Value
Age, years, mean ± SD	38.7 ± 12.9
Male sex, n (%)	12 (70.6)
Married, n (%)	12 (70.6)
Currently employed, n (%)	8 (47.1)
Age at OCD onset, years, mean ± SD	25.64 ± 9.26
Duration of illness, years, median [IQR]	10 [5.5–18.5]
Predominant compulsion type: washing/cleaning, n (%)	10 (58.8)
Baseline Y-BOCS, mean ± SD	26.65 ± 6.05
Baseline HAM-D-17, mean ± SD	11.58 ± 5.90
Baseline CGI-Severity, modal category, n (%)	Moderately ill, 8 (47.1)
Comorbid psychiatric illness, n (%)	14 (82.4)

Clinical outcomes

The mean Y-BOCS score fell from 26.65 ± 6.05 to 22.41 ± 6.89, a mean percentage reduction of 16.67% ± 12.90% ($p < 0.001$). The mean HAM-D-17 score

fell from 11.58 ± 5.90 to 8.11 ± 4.79, a mean reduction of 29.55% ± 24.07% ($p < 0.001$) (Table 2). Two patients (11.8%) were responders (≥ 35% Y-BOCS reduction), one (5.9%) was a partial responder (25–34%), and 14 (82.4%) improved by less than 25%; thus three patients (17.6%) had a reduction of at least 25% (Table 3). Mean CGI-Improvement was 2.88 ± 0.99. Greater percentage reduction in Y-BOCS was associated with greater percentage reduction in HAM-D-17 (Pearson $r = 0.74$, $p = 0.0006$).

Table 2. Change in symptom scores from baseline to end of treatment (n = 17)

Measure	Baseline	End of treatment	Mean % reduction ± SD	p (paired t-test)
Y-BOCS	26.65 ± 6.05	22.41 ± 6.89	16.67 ± 12.90	< 0.001
HAM-D-17	11.58 ± 5.90	8.11 ± 4.79	29.55 ± 24.07	< 0.001

Table 3. Y-BOCS response categories (n = 17)

Category	n (%)
Response (≥ 35% reduction)	2 (11.8)
Partial response (25–34% reduction)	1 (5.9)
Reduction of ≥ 25% (response + partial response)	3 (17.6)
Reduction of < 25%	14 (82.4)

Adverse effects

There were no serious adverse events (Table 4). Mild, transient headache was the most common adverse effect (5 patients, 29.4%). Fatigue and nervousness were each reported by one patient (5.9%). All resolved spontaneously.

Table 4. Adverse effects during tDCS (n = 17)

Adverse effect	n (%)
Headache	5 (29.4)
Fatigue	1 (5.9)
Nervousness	1 (5.9)
Serious adverse events	0

Table 5. Individual patient data [template: to be completed from patient-level records before submission]

Patient	Age/sex	Illness duration (years)	Predominant symptoms	Concurrent medication	Y-BOCS pre → post	HAM-D-17 pre → post	CGI-I	Adverse effects
1								
2								
…								
17								

Discussion

In this series of 17 patients with SRI-resistant OCD, a 10-session course of add-on cathodal pre-SMA tDCS was followed by an average 17% reduction in Y-BOCS score, which is statistically detectable but modest, and by a larger proportional fall in depressive symptom scores. Only three patients (17.6%) achieved at least a 25% Y-BOCS reduction and two (11.8%) met the ≥ 35% response threshold, and mean end-of-treatment Y-BOCS (22.4) remained in the moderate-to-severe range. The results therefore suggest a limited average effect of this protocol when assessed immediately after the course.

Several features of the protocol may have constrained the effect. The course comprised 10 sessions, fewer than in some published protocols, and outcomes were measured straight after the last session. Other studies have reported benefit that develops or persists over the weeks after stimulation, so an end-of-treatment assessment could understate the eventual response. Optimal polarity, montage, current dose and number of sessions remain unsettled [7,13,14], and sham-controlled trials have given mixed results [12–14]. This series cannot address those questions.

Improvement in OCD and depressive symptoms went together ($r = 0.74$). Baseline depression scores were in the mild range on average, so the HAM-D-17 change may reflect a general mood effect of stimulation, expectancy, or the natural course, rather than a specific anti-obsessional action. The proportional fall in HAM-D-17 scores should also be read cautiously because of the low baseline values and wide variability.

Tolerability was good. Headache was the most frequent effect, followed by single reports of fatigue and nervousness, and all were mild and self-limited, in keeping with the known tDCS side-effect profile

[8]. No serious adverse event occurred. Together with its portability and low cost, this makes tDCS a feasible option for outpatient use where monitored infusion facilities are not available, although the present data do not show that it matches the effect size of more intensive treatments.

Limitations

This series has no sham or other comparison group, so expectancy, placebo effects and spontaneous change cannot be excluded. Patients chose tDCS themselves, which may select for those who preferred a non-pharmacological, non-infusion option. The design was open-label [authors to confirm whether raters were blinded]. The sample is small and from a single centre, and subgroup analysis by symptom dimension was not possible. Outcomes were measured only before and at the end of treatment, so durability of benefit and any delayed effects are unknown. Patients were on varied stable medication regimens that could not be standardised. The work was derived from a postgraduate dissertation and was not prospectively registered in a clinical trials registry.

Conclusion

In this case series of treatment-resistant OCD, a 10-session course of add-on cathodal pre-SMA tDCS was well tolerated and followed by a modest average improvement in obsessive-compulsive and depressive symptoms, with only a minority of patients reaching response by the end of treatment. Sham-controlled trials with longer or repeated courses and follow-up are needed to establish efficacy and the optimal protocol.

Declarations

Ethical approval and consent: The study was approved by the Institutional Ethics Committee and Scientific Research Review Board, Sardar Patel Medical College, Bikaner, and followed the Declaration of Helsinki and its amendments. All participants gave written informed consent. [Authors to confirm that consent covers publication of anonymised data.]

Related work: The 17 patients reported here are the tDCS arm of a preference-based comparative cohort of 39 patients, reported separately [15]. No between-group comparison is made in this report.

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Data availability: De-identified data are available from the corresponding author on request.

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