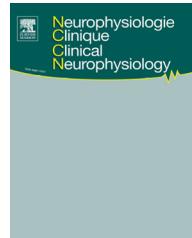




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ORIGINAL ARTICLE

# Hospital production cost of transcranial direct current stimulation (tDCS) in the treatment of depression

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Received 23 September 2018; accepted 8 November 2018

## KEYWORDS

Cost;  
Depression;  
Health Economics;  
Neurostimulation;

## Summary

**Objectives.**—Due to its ease of use, tolerance, and cost of acquisition, transcranial direct current stimulation (tDCS) could constitute a credible therapeutic option for non-resistant depression in primary care, when combined with drug management. This indication has yet to receive official recognition in France. The objective of this study is to evaluate the production cost of tDCS for the treatment of depression in hospitals, under realistic conditions.

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Psychiatry;  
TDCS

**Methods.** — The methodology adopted is based on cost accounting and was validated by a multidisciplinary working group. It includes equipment, staff, and structural costs to obtain the most realistic estimate possible. We first estimated the cost of producing a tDCS session, based on our annual activity objective, and then estimated the cost of a 15-session treatment program. This was followed up with a sensitivity analysis applying appropriate parameters.

**Results.** — The hospital production cost of a tDCS depression treatment program for a single patient was estimated at €1555.60 euros: €99 in equipment costs, €1076.95 in staff costs, and €379.65 in structural costs.

**Conclusion.** — This cost analysis should make it possible to draw up pricing proposals in compliance with regulations and health policy choices and to develop health-economic studies. This would ultimately lead to official recognition of tDCS treatment for depression in France and pave the way for studying various scenarios of coverage by the French national health insurance system.

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## Introduction

Depressive disorders are becoming one of the most frequent disorders in the world, according to the World Health Organisation (WHO) [2], and they create a substantial functional handicap [33]. In spite of effective pharmacological and psychotherapeutic therapeutic measures, only one third of all patients with a major depressive disorder (MDD) achieves clinical remission after a well-conducted first-line antidepressant treatment [39]. For 70% of all patients with MDD, four phases of treatment are needed to achieve remission [39]. In patients who have used more than one antidepressant, 80% relapse within one year [18]. A partial response or resistance to antidepressant therapy is linked with a higher risk of relapse, chronicity, suicidal behavior [39,40], and altered quality of life [33].

Due to poor tolerance, most depressed patients (63%) comply poorly with medication regimens [41]. Approximately 85% of all patients on SSRIs, which are first-line antidepressant treatments recommended for MDD, experience at least one side effect during the early stages of treatment [25].

To overcome these obstacles of resistance, tolerance, and medication compliance, it is essential to offer therapeutic alternatives, including noninvasive neuromodulation techniques like transcranial direct current stimulation (tDCS). By applying a low direct current (1–2 mA), tDCS stimulates and modifies neuronal response.

Using tDCS headgear, electrodes are positioned so as to target specific brain regions. The antidepressant effects of tDCS on the dorsolateral prefrontal cortex have been suggested since 2006 [8], and since corroborated by numerous studies [5–7,10,20,30,31,35,38]. Most studies indicate that active tDCS is significantly more effective than sham tDCS in terms of MDD alleviation, clinical response, and remission of characterized depressive states [3,4,12,21,26,32,42].

Current recommendations present grade-B evidence for the treatment of MDD—in treatment-naïve patients or those receiving treatment but exhibiting no resistance—through fifteen 20- to 30-minute sessions of tDCS at 2 mA during

which the anode is positioned over the dorsolateral prefrontal cortex and the cathode over the right prefrontal orbital cortex [29]. Such stimulation may counter hypofunction in MDD [8,9]. Effects of tDCS are exerted at the cortical level, close to the electrodes and also on deeper structures like the hippocampus [27,28]. Placebo-controlled trials have suggested the value of tDCS for treatment-resistant depression [3,5,19,35], and it has been shown to be well tolerated [13]. Nevertheless, a high level of resistance to treatment would indicate a lower response to tDCS [11,36,37]. Thus tDCS appears to be a promising therapeutic strategy, when combined with drug management, for the treatment of depression.

The required apparatus for tDCS are Class IIa medical devices [17] used in psychiatry for research purposes as well as in certain complex clinical situations, such as third-line therapy. The indications for tDCS are currently not recognized by French health authorities. Clinical efficacy is the key to integrating new technology into the therapeutic arsenal. At the same time, economic evaluation is an increasingly important prerequisite for the reimbursement of treatments utilizing health technology, regardless of the indication. To the best of our knowledge, no health economic evaluation of tDCS had previously been conducted anywhere in the world, in contrast to repetitive transcranial magnetic stimulation (rTMS) and electroconvulsive therapy (ECT) [23].

Given this context, the objective of this preliminary study is to evaluate the production cost of tDCS for hospital-based MDD treatment, under realistic conditions. It is supplemented by a sensitivity analysis considering pertinent parameters.

## Methods

### General methodology

The methodology adopted is mainly based on cost accounting and was developed by a multidisciplinary working group

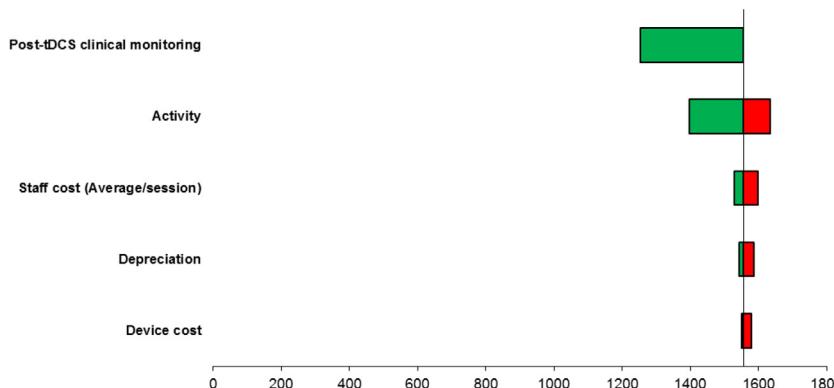


Figure 1 Tornado diagram showing uncertainty generated on costs according each parameter.

of clinicians, public health physicians, pharmacists, administrative and financial managers, and health economists. It involved a review of the international literature and collective approval of cost categories included. We applied a pragmatic, comprehensive approach that considered financial, economic, clinical, institutional, and organizational aspects to obtain as realistic an estimate as possible for real-life hospital settings. This work was conducted in a university hospital. Costs were divided into three categories: equipment, staff, and structural. We based the estimate of each cost on practices within our own establishment and on current regulations.

Our estimates for the three cost categories were used to calculate the production cost of a tDCS session, based on our annual volume of activity and the duration of a single session. We also estimated the cost of a complete 15-session treatment program for a single patient. Finally, to evaluate the applicability of our estimates, which were based on conditions in our own establishment, we conducted a univariate deterministic sensitivity analysis of factors likely to impact production cost, i.e., equipment purchase price, depreciation period, annual number of sessions, and hourly staff costs. The results of this analysis are summarized in a tornado diagram (Fig. 1) showing uncertainty generated by each parameter [24,38].

### Estimated resource requirements for implementation of tDCS treatment and bases of valuation

#### Equipment

The tDCS device consists of a stimulator with accessories (cap, electrodes, ear clips, and cables).

For the purposes of estimation, we considered all equipment needed to administer tDCS treatment (as performed at Nantes University Hospital) as well as the associated maintenance.

Optional add-ons are sold by providers but are not essential for the treatment of depression, so they were excluded from this study. We considered the purchase price of the tDCS device used in our hospital. Prices indicated include a 20% value-added tax.

#### Staff costs

We included the cost of medical and paramedical staff required to administer treatment, monitor patients, and maintain equipment (e.g., washing of electrodes and cap and charging of stimulator). The average duration of first and following sessions were considered. We assumed the first session to last 45 minutes, which included time to receive the patient and set up the equipment. Following sessions were deemed to last 30 minutes, in line with tDCS best practice recommendations [34]. These estimated session durations were further lengthened by 30 minutes to account for post-tDCS clinical surveillance.

The documentary sources consulted for this cost category were:

- guidelines prepared by the French Technical Agency for Information on Hospital Care (*Agence Technique de l'Information sur l'Hospitalisation*) with data from a sample of French establishments providing medical, surgical, and obstetric care [1];
- reference grids and legal texts related to working hours in public hospitals;
- and French M21 budgetary and accounting nomenclature and guidelines for public health establishments [22].

#### Structural costs

Structural costs or charges include expenses associated with the elements of general hospital logistics and organization: the computer system (e.g., IT, network, software, and technical assistance); patient reception and management (e.g., administrative procedures and invoicing); room and board services; maintenance; building upkeep (e.g., cleaning, technical services, maintenance, and depreciation); general administrative services; financial management (e.g., economic and loan management); and personnel management (e.g., personnel and labor relations as well as medical affairs management).

The main documentary source consulted for this cost category was the set of hospital accounting guidelines published on January 1, 2012, including requirements for the restated financial accounts that all public hospitals must prepare, which provide an objective measure of structural costs [14].

## Results

### Equipment costs

The price of a tDCS device varies from €8000 to €14,000 (incl. tax), which covers the cap, electrodes, ear clips, cables, and an EEG add-on feature. Our establishment acquired one for €9000 (incl. tax), which is an average price. Maintenance includes after-sales service for €840 (standard exchange if battery is defective), changing of caps after one year of use, changing of cables after one and a half years, and changing of electrode pairs after they have been used 100 times.

Based on information from the manufacturer, we may assume expenses of €2400 per year for consumables (sponges, etc.), without discounts, and €840 every two years for after-sales service. Thus we estimate a total maintenance cost of €5640 every two years.

The depreciation of the equipment, recorded on the balance sheet and income statement, accounts for wear and tear, technological innovation, and other factors affecting its monetary value. The depreciation method applied by our hospital is linear, making it possible to spread the cost of tDCS device acquisition over a five-year period. The depreciation period was defined by our hospital in light of current manufacturer data on equipment performance and technological developments prompting period replacement of equipment. The depreciation rate used was 1/5 (=20%), so the calculated annual depreciation was €1800.

We projected an annual volume of 700 tDCS sessions (approximately two sessions per working day) for the treatment of depression in our hospital ward, taking into account logistical factors (sharing of premises) and human factors (staff availability) unlikely to vary over the next five years.

The annual cost of equipment use due to depreciation is €1800. For an annual volume of 700 tDCS sessions, this equates to a cost of €2.57 per session, during the depreciation period of the equipment. After that period, equipment costs should only correspond to maintenance: €5640 every two years, or €4.02 per session in our case.

This yields an estimated total equipment cost per session of €6.60 (=€4.02 + €2.57) during the five-year depreciation period, and €4.02 per session thereafter until acquisition of a new device. Our per-session cost estimate for tDCS treatment applies to the first five years following equipment purchase.

### Staff costs

In practice, we distinguish first and following sessions: the first lasts about 45 minutes while subsequent ones last about 30 minutes each. In addition, post-tDCS clinical monitoring, whose duration varies according to the stimulation parameters used, lasts about 30 minutes. This is the time needed for the patient to recover from the fatigue caused by the session. Hence the total time spent by the patient in a treatment setting should not exceed 1 hour and 15 minutes for the first session and 1 hour for subsequent sessions. Paramedical and medical staff costs must reflect these durations.

Data suggest that one trained technician as well as a nurse or a physician should be present for the procedure

[29]. Although tDCS is very well tolerated, the medical unit should be prepared to deal with possible burns or headaches. Staff training for tDCS is relatively simple, and the supplier can provide initial or follow-up training to physicians upon request.

The following average hourly staff costs were estimated by dividing the annual cost for each category of personnel by the stipulated annual number of working hours for the category in question: €35.29 for nurses, €54.99 for hospital practitioners, €28.65 for medical assistants, and €22.34 for resident. These four categories account for all personnel participating in tDCS sessions within our hospital. The average hourly cost for the medical staff in attendance for the procedure—i.e. hospital practitioner, medical assistant, and resident—is therefore €35.33. However, during a session, the presence of both a nurse and a physician is required. Thus the total average hourly staff cost for all but the first session is €70.62 (sum of average hourly cost for nurse and average hourly cost for medical staff). For the first session, the average is €88.27. The sensitivity analysis accounted for variation in staff costs due to the presence of either a resident or a hospital practitioner.

### Structural costs

Structural costs or charges include costs related to the general logistics and organization of the health care facility, as described in 'Methods' above. Table 1 provides a detailed breakdown for this category.

### Estimated overall cost of tDCS session and complete 15-session program

Table 1 offers a cost breakdown for a single tDCS session and a 15-session treatment program. Table 2 shows how each of the three cost categories contribute to the production cost for a 15-session tDCS treatment program.

### Sensitivity analysis

The variables considered for the sensitivity analysis are given in Table 3, together with assumed values. See the tornado diagram (Fig. 1) for the results of this analysis.

### Discussion

The objective of this preliminary study was to evaluate the production cost of tDCS for treating MDD under realistic hospital conditions. Our calculations indicate an estimated average cost for a 15-session hospital-based tDCS depression treatment program of €1555.60. In addition to providing the first known estimate for such treatment in the literature, our work stands out because it relied on the collaboration of a multidisciplinary working group, considered actual practice, and applied a thorough breakdown of direct and indirect costs.

Our work also has its limitations. Many parameters could alter our cost estimate by over- or underestimating them. For equipment costs, this mainly concerns the initial price of the equipment and add-ons, the model of depreciation

**Table 1** Breakdown of transcranial direct current stimulation (tDCS) treatment costs (in euros; all taxes included; no discount).

<i>Equipment costs</i>	
tDCS device	€ 9000
Maintenance (battery and accessories; every 2 years)	€ 5640
Depreciation (years)	5
Total equipment cost, per session	€ 6.6
<i>Staff costs</i>	
Nurse, per hour	€ 35.29
Hospital practitioner, per hour	€ 54.99
Medical assistant, per hour	€ 28.65
Resident, per hour	€ 22.34
Medical staff average (i.e., nurse excluded), per hour	€ 35.33
Total average staff costs, for session 1	€ 88.27
Total average staff costs, for each of sessions 2–15	€ 70.62
<i>Structural costs</i>	
Information system, per year	€ 4333
Information system, per session	€ 6.19
Patient reception, per patient	€ 10.06
Patient reception, per session	€ 0.67
Patient room and board, maintenance, property structure (for 10 m <sup>2</sup> /year)	€ 3761.71
Patient room and board, maintenance, property structure, per session	€ 5.37
Administrative service, per euro charged	€ 0.14
Charge	€ 78.39
Administrative service, per session	€ 10.97
Staff management, per full-time equivalent	€ 1868.58
Staff management, per session	€ 2.1
Total structural costs, per session	€ 25.31
Overall cost of session 1 (1 h 15 min)	€ 120.18
Overall cost of each of sessions 2 to 15 (1 h)	€ 102.53
Overall cost of complete 15-session treatment program	€ 1555.60

**Table 2** Summary of costs of transcranial direct current stimulation (tDCS) treatment program for a single patient (in euros).

	Unit cost, session 1 (1 h and 15 min)	Unit cost, each following session (1 h)	Total cost, sessions 2–15	Total cost, 15-session treatment program
Equipment costs	€ 6.60	€ 6.60	€ 92.40	€ 99
Staff costs				
Nurse	€ 44.11	€ 35.29	€ 494.06	€ 538.17
Doctor	€ 44.16	€ 35.33	€ 494.62	€ 538.78
Structural costs	€ 25.31	€ 25.31	€ 354.34	€ 379.65
Total	€ 120.18	€ 102.53	€ 1435.42	€ 1555.60

applied, the annual volume of tDCS sessions, whether the medical establishment chooses to invest in new equipment, changing stimulation parameters, and technological innovations that can affect equipment pricing. Differences in the qualifications of staff designated to participate in tDCS sessions and in the cost of training will likewise modify the cost per session. The sensitivity analysis confirms these statements and shows that, by increasing the annual volume of tDCS sessions in our center, we may lower the total cost of a 15-session treatment program to €1395.90, i.e., 89.7% of the current production cost.

Finally, indirect structural costs may also vary according to the geographical configuration of the medical complex

(e.g. supply costs being higher for multi-site hospitals), balance sheet details (e.g. dates of infrastructure renewals), logistical agility, and overall hospital management practice. It was partly to curb such biases that we chose to consider actual hospital conditions and rely on a multidisciplinary team.

In a previous study on rTMS, we estimated the hospital production cost for a 15-session rTMS depression treatment program to be €1932.94 including VAT: €503.55 for equipment, €1082.75 for staff, and €346.65 for structural expenses [15]. Hence we estimate that tDCS is cheaper than rTMS for the treatment of depression. How frequently equipment is used can also significantly affect treatment cost.

**Table 3** Sensitivity analysis variables.

Variable	Nantes University Hospital	Min	Max
Device cost	€9000	€8000	€14,000
Depreciation, years	5	3	7
Activity level	17.5% (700 sessions = 360 h)	12.5% (500 sessions ≈ 258 h)	100% (4000 sessions = 2066 h or ≈ 1 year of full-time use, 40 h/wk)
Staff cost (average/session)	€71.79	€58.59	€91.78
Post-tDCS clinical monitoring, min	30	15	30

However, not only the production cost but also the effectiveness of treatment must be taken into account.

Due to the cheap cost and safety of tDCS, this technique may be used by numerous practitioners outside the regulatory aspect, as seen with rTMS. On the one hand, it may be an interesting therapeutic option for in and outpatients, with “at-home” tDCS devices also being available. On the other hand, clinicians should be very cautious when they wish to propose innovative treatment, especially when some of these devices are easy to use and inexpensive. If so, these devices are also likely to be used by the general population in nonclinical settings and under unqualified supervision—a phenomenon that if kept unchecked could be very harmful for users and could mar the reputation of neurostimulation techniques [41].

The level of French national health insurance coverage for tDCS treatment has yet to be fixed in France. The question of reimbursement has yet to be resolved for tDCS, as for rTMS, which has yet to receive official recognition in France [16]. Drawing on the potential reimbursement options we outlined for rTMS depression treatments, we suggest that tDCS be invoiced either within the scope of the global allocation or as outpatient activity, provided that other acts are associated with it and that they fulfil the conditions stated in the French health ministry’s Instruction No. DGOS/R/2010/201 of June 15, 2010.

Complementary health economics and multicenter studies are needed to determine the efficacy of tDCS in the management of depression. This is the objective of the DISCO study currently under way.

## Conclusion

The present cost analysis should serve as a basis for similar studies under other conditions (e.g., in outpatient centers, specialized establishments, and clinics) to obtain a more general estimate and evaluate cost variability. This would allow pricing proposals to be drawn up, in accordance with regulations and health policy choices, and enable further development of health economic studies.

Ultimately, these steps will make it possible to formally define a tDCS medical procedure, in order to promote the technique in France and consider how it might be covered by the French national health insurance system.

## Funding

This work has been supported by a grant from the French Health Ministry for the DISCO study PRME-2017-0097.

## Disclosure of interest

The authors declare that they have no competing interest.

## Acknowledgments

The authors wish to thank warmly Hélène Prod’homme, Vincent Gaborit, and Chloé Fourage for their assistance. They also wish to thank Jason Miller for his editing assistance.

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