Electroconvulsive Therapy, The Placebo Effect and Informed Consent

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PAPER

Electroconvulsive therapy, the placebo effect and informed consent

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ABSTRACT

Major depressive disorder is not only the most widespread mental disorder in the world, it is a disorder on the rise. In cases of particularly severe forms of depression, when all other treatment options have failed, the use of electroconvulsive therapy (ECT) is a recommended treatment option for patients. ECT has been in use in psychiatric practice for over 70 years and is now undergoing something of a restricted renaissance following a sharp decline in its use in the 1970s. Despite its success in treating severe depression there is continued debate as to the effectiveness of ECT: in some studies, it is argued that ECT is marginally more effective than sham ECT. In addition, there is still no clear explanation of how ECT works; among the range of hypotheses proposed it is claimed that ECT may work by harnessing placebo effects. In light of the uncertainties over the mechanism of action of ECT and given the risk of serious side effects that ECT may produce, I contend that the process of informed consent must include comprehensive accounts of these uncertainties.

I examine the possible consequences of providing adequate information to potential ECT patients, including the consideration that ECT may still prove to be effective even if physicians are open about the possibility of it working as a placebo. I conclude that if we value patient autonomy as well as the professional reputation of medical practitioners, a fuller description of ECT must be provided to patients and their carers.

Electroconvulsive therapy (hereafter ECT) is a form of psychiatric treatment that involves the electrical inducement of seizures in patients. ECT was first used in 1938 by the psychiatrist Ugo Cerletti in Rome for the treatment of schizophrenia; by the 1940s it had been introduced into the UK and USA and used in the treatment of a range of psychiatric illnesses (in particular, schizophrenia and bipolar disorder).[1] Its reputation as a particularly aggressive form of psychiatric treatment was cemented in the 1975 film *One Flew over the Cuckoo's Nest* and its use (certainly in the UK and USA) declined sharply in the 1970s.[1]

ECT has now been refined and is undergoing something of a (restricted) renaissance in the UK and USA where it is mainly used in the treatment of major depression; in particular, it is reserved only for those patients whose depression is particularly severe and recurrent and for whom other treatments have proven ineffective. Informed consent for the administration of ECT is now a requisite in the UK and the USA and WHO states that 'ECT should be administered only after obtaining informed consent'.[2] The specifics of what comprises 'informed' consent for such patients are the concern of this paper. I shall be less concerned with the related but significant problem of determining patient 'capacity' to elect for ECT treatment.

There is empirical consensus that the explanation for the effectiveness of ECT is not yet understood.[1] In addition, studies examining the effectiveness of ECT have been met with a mixed response: some report that ECT is a 'valid therapeutic tool';[3–5] others contend that ECT is only more effective than sham ECT during the treatment period.[6–8] It has also been contended that the methodological shortcomings in creating adequate placebos for comparison of ECT render evidence based assessments highly problematic; as early as 1959, researchers into the mechanism of action of ECT for depression hypothesised that 'the therapeutic action' may be owed entirely to placebo responses including 'the psychological meaning of the treatment to the patient, or the unusual amount of care and attention involved in the experimental procedures'.[9] The claim that ECT may work by eliciting a therapeutic *placebo* response in patients with severe depression is a hypothesis that many empirical researchers argue is both credible and significant.[7–10]

The aim of this paper is not to enter into a detailed discussion of the correct interpretation of these trials; rather, the goal is to highlight the *matter of fact* that persistent controversy remains with regard to: (a) the efficacy of ECT and (b) how it works, including whether ECT owes its effects to a placebo response (ie, ECT is 'placebogenic'). After delineating the considerable range of issues and debate over ECT, I conclude that patient information needs to improve: existing guidelines and practice fall short of the ethical dictum of patient autonomy. Patients ought to be informed that there is no current explanation as to how ECT works and, in addition, they should know of the controversial, long-standing claim that ECT may work as a placebo. I argue that informing patients that ECT may work as a placebo may not undermine the effectiveness of the treatment even if ECT is placebogenic[11] nor may it inhibit patients from electing the treatment. It is the contention of this paper that if we value informed consent in clinical encounters it is paternalistic (at best) and negligent (at worst) to fail to disclose this information.

ECT AND MAJOR DEPRESSIVE DISORDER

In order to appraise the current guidelines on informed consent for ECT, it is important to say

something about the treatment procedure and its side effects. ECT patients are first given a short-acting general anaesthetic, a muscle relaxant (to prevent musculoskeletal injury) and an agent (usually atropine) to inhibit salivation.[1] In the majority of cases of ECT administration, electrodes are placed bilaterally across the head and an electrical current is passed through the brain, causing a seizure; the voltage required must be above a certain threshold in order for the seizure to occur and for it to be effective. In the UK, this treatment is administered to patients twice per week for 3–6 weeks; in the USA, treatment is typically three times per week for 3 or 4 weeks. On average, patients receive six to twelve treatments.[1] In the USA, 'maintenance' treatments may be performed at weekly, fortnightly or monthly intervals; this practice is not endorsed in the UK.[1 12]

Immediately following treatment, all ECT patients experience confusion which may last for up to 1 h; post-treatment, it is estimated that around three-quarters of patients report fatigue; headaches occur in about half of patients; and a fifth of patients report muscle aches lasting several hours.[13] Cardiac complications are also deemed to be 'common' (and occur in an estimated 6% of geriatric patients).[14] The most common side effects include short-term and/or long-term memory loss: most patients experience problems in retaining new information (anterograde amnesia) and in recalling events that occurred in the weeks preceding the treatment (retrograde amnesia). It has been reported that these symptoms dissipate in the weeks and months following treatment;[15] however, some patients experience more severe retrograde amnesia, extending back years.[16–18] It has also been argued that the potential for cognitive impairment including enduring autobiographical memory loss is under-reported in the empirical literature due to lack of long-term follow-up studies.[15 19–21]

ECT AND THE PLACEBO EFFECT

A major (and ongoing) discussion has arisen in empirical reviews over the effectiveness of ECT including whether sham ECT is significantly less effective than ECT.[7–10] While some studies contend that ECT is an 'excellent treatment of severe depression'[3 4] these reports have been challenged on three grounds. First, it has been argued that ECT is only effective in the time period when it is administered.[6 8] In support of this, studies purport to show that ECT is not effective as a long-term treatment;[6] in addition, it has been claimed that the relapse rate of ECT is not significantly different from discontinuation of antidepressant medication.[22] Second, it has been argued that the difference between ECT and sham ECT is, at best, 'modest'.[8] Correlatively, it has been observed that there is an 'unexpectedly high rate of response of sham ECT'[10] and this, it has been claimed, should alert practitioners to the role of other (perhaps placebogenic features) in both ECT and sham ECT procedures.[7–9] Third, reviews of meta-analyses have criticised the adequacy of placebo controls in the testing of ECT: this is particularly important in establishing the effectiveness of ECT and in establishing how it works.[7–10] In fact, there are particular methodological and ethical constraints in providing adequate placebos to test the efficacy of ECT and it is worth pausing to reflect on their importance.

In medical trials, it is considered that legitimate placebo controls should mimic all the observable effects of the therapy under scrutiny; as Howick notes, a placebo control must satisfy the following conditions:

1. The placebo control contains all the relevant non-characteristic features of the test treatment t, to the same degree that they are present in the experimental treatment process;
2. The placebo control has no additional relevant features over and above the non-characteristic features of the experimental treatment.[23]

In the case of ECT, providing a placebo intervention that satisfies both of the conditions would involve the task of providing a form of 'non-treatment' that mimicked all of the common side effects of ECT: this would include confusion after treatment, headaches, muscle aches and even memory loss.

In the sham ECT arm of ECT trials, patients receive the same number of consultations as ECT patients and undergo anaesthesia but they do not experience the side effects that genuine ECT treatment induces. Given that patients will be made aware of the common side effects of '*bona fide* ECT', all the patients involved in trials with any form of sham ECT that does not mimic such effects may be able to 'break-blind', that is, to guess that they have been given the sham treatment. This, it has been charged, is a serious limitation of ECT research.[7–10] Patients' ability to guess that they have received a sham treatment may influence expectations (and therefore the effects of the treatment under scrutiny). While it might be argued that *bona fide* ECT procedures are likely to have more impressive results than placebogenic treatments, there are additional concerns if patients break-blind: if patients guess that they have received the sham treatment this can undermine trials by the covert decision on the part of patients to seek and employ additional genuine treatment.[8] In fact, this has been a key criticism of ECT trials whereupon patient 'cross-over' from sham to ECT treatment are reported.[3 8 10]

With regard to these challenges, it might be asked, in a research context: Would it be ethically permissible to provide a placebo control that mimicked the serious side effects of ECT? The revised Declaration of Helsinki declares that:

> [A] placebo controlled trial may be ethically acceptable even if proven therapy is available, under the following circumstances
>
> > Where for compelling and scientifically sound methodological reasons its use is necessary to determine the efficacy or safety of a prophylactic, diagnostic or therapeutic method.[24]

However, as Howick notes, there are no guidelines on what might constitute 'compelling' grounds for the use of any such (legitimate) placebo controlled trials.[23] To reiterate: any compelling sham ECT would cause (among other possible side effects) confusion, headaches, muscle aches and memory impairment; so, even if it were possible to provide such a range of tangible effects that did not cause any additional 'damage' to the patient or influence the outcome of the trial in any other manner, such procedures may be deemed unacceptably risky to patients even in a research context. It is also worth noting that it has been argued that it is epistemologically and ethically reasonable only to conduct trials of treatments with comparisons of the best treatments available (and not placebos); ECT is often (though problematically) declared to be 'the best treatment available' for severe depression. Given that it is treatment that poses long-term risk of cognitive impairments and memory loss,[20 21 25] there are certainly grounds for querying whether any other form of treatment for severe depression should be tested against ECT.

Finally, and importantly, the issue of how ECT works (to the debated extent that it does) is still declared uncertain in the empirical literature. While hypotheses explaining the effectiveness of ECT have been proposed none have received robust

support and there is consensus that there is still no explanation for the mechanism of action of ECT.[1 7–10 26–28] Among the range of claims, some theorists assert that ECT may stimulate neuronal growth;[25] others simply claim that 'the convulsions' are curative;[3] and the theory that ECT may work by harnessing placebo responses has also been embedded in the empirical literature for over 50 years.[9 10] In this last regard, as noted, it has been speculated that sham ECT is effective because of the range of placebogenic—or 'positive care effects'—that it invokes.[29] These effects include: the 'surgical' intervention; the use of high technology treatment; the attention provided by the medical staff; and the prior belief in the effectiveness of the treatment. It may be that the additional side effects induced by ECT (including patient expectations, in light of these effects) further enhance such (therapeutic) placebo responses. In this regard, it is also pertinent to observe that depression is a condition that may be particularly susceptible to placebo responses.[30 31]

ECT AND CURRENT CLINICAL GUIDELINES

At the outset, we can note that in both the UK and USA doctors are instructed that there should be a presumption of capacity for patients suffering from depression to reach decisions about their treatment.[28 32] Treatments without consent are rare but do occur in both the UK and USA (such cases are typically restricted to those patients considered to lack capacity and who are continually suicidal).[28 32] I will consider the prevailing guidelines before examining their discordant shortcomings in light of current medical research.

In the UK, the tenets that comprise the principle of 'informed consent' include: '(b) discuss with patients what their diagnosis, prognosis, treatment and care involve; (c) share with patients the information they want or need in order to make decisions'.[33] The specific guidelines for ECT in the UK recommend that: 'Someone who is capable of making a decision about their treatment should decide, after discussion with the doctor, whether or not they want to give their consent to have ECT.' The guidelines further stipulate that *'full and appropriate information* about ECT should be given…'[33] and that consent must be given at each stage throughout the period of treatment. The NICE patient and practitioner guidelines on ECT also include the following: 'Although ECT has been in use since the 1930s, how it works is still not fully understood'.[34] While this description might appear to demonstrate a degree of honesty it does not go far enough, and arguably is something of a sleight of hand: far from being *'fully* understood' the empirical accounts inform us that ECT is not even partially understood.

In the USA, physicians are required to discuss with their patients:

- The nature and purpose of a proposed treatment or procedure
- The risks and benefits of a proposed treatment or procedure
- Alternatives (regardless of cost…)
- The risks and benefits of the alternative treatment or procedure
- The risks and benefits of not receiving or undergoing the treatment procedure.[35]

The American Medical Association guidelines declare that 'The physician has an ethical obligation to help the patient make choices from among the therapeutic alternatives consistent with good medical practice'; furthermore, physicians 'should respectfully disclose all relevant medical information to patients.'[36] As in the UK, the American Psychiatric Association (APA) stipulates that 'care should be taken to ensure that the informed consent process continues across the complete period during which ECT is administered'.[32] The APA advises that 'The scope and depth of informational material as part of the consent document should be sufficient to allow a reasonable person to understand and evaluate the pertinent risks and benefits of ECT as compared to treatment alternatives'.[32] The sample information sheet in the APA recommendations includes the following:

> During ECT, a small amount of electrical current is sent to the brain. This current induces a seizure that affects the entire brain, including the parts that control mood, appetite, and sleep. ECT is believed to correct biochemical abnormalities that underlie severe depressive illness. We know that ECT works....[32]

The declarative explanation that ECT is 'believed to correct biochemical abnormalities' is far from 'fully informative'—it is misleading. First, no 'biochemical' abnormality theory of the brain has been established as an explanation for depression.[37] Second, as in the case of the UK guidelines, if we value the very idea of informed consent, ECT patients (or those making decisions on their behalf) should surely be privy to the matters of fact that: (a) there is continued controversy over the effectiveness of ECT; (b) there is orthodox scientific consensus that there is currently *no* acknowledged explanation for ECT; and (c) there is a serious (mainstream) debate over whether the response to ECT may be a placebo response.

RECOMMENDATIONS FOR AUTHENTIC INFORMED CONSENT FOR ECT

The importance of informed consent in clinical practice is stringently asserted in medical ethics codes. However, 'fully' informed consent would mean detailing everything that is known about particular treatment options. While this is not a realistic proposal it is incumbent on physicians to ask: 'What is a medically relevant fact for *this* patient if they are to agree to this form of treatment?' This opens up the following questions: (i) 'What do all patients need to know if they are make decisions and to understand information on the effectiveness and side effects of a treatment?' and (ii) 'What do individual patients *consider* to be significant with regard to treatment options?' In the case of a therapy—such as ECT—where the mechanism of action is not known, for which there is controversy over its effectiveness, *and* for which there are significant and serious side effects, it seems clear that patients deserve to know this information. We can speculate scenarios in which this information might arise if it is not forthcoming, and if physicians are not honest at the outset this might jeopardise patient trust. Consider, for example, that a patient might consider the use of electrical currents as a particularly threatening form of treatment and such a patient may ask probing questions about this aspect of the treatment. In order to answer such questions, the physician would need to inform the patient that it is not yet clear whether the electrical current is even a curative component of the treatment (since the mechanism of action of ECT is still disputed). In addition, in the case of information that might, on the face of it, seem to the physician to be irrelevant, such information may be interpreted differently by individual patients: if one patient has a particular anxiety or questions about the dosage of anaesthesia in the procedure then additional information needs to be tailored to this patient. It does seem correct to speak of a core of relevant or significant information that ought to be relayed to patients and that can have a bearing on patient decisions;[38] but how that information is transmitted will need to be modified for

different patients. In addition, there may be no rules of thumb about the idiosyncrasies that may be involved in individual information requests and which may impact on patient decision making. To reiterate: there is a whiff of psychological naivety in dicta about informed consent that do not pay due attention to how patients perceive treatments, and what different patients may regard as significant facts for them. The burden is on the medical community not only to supply accurate information but (especially in an internet age, where patients can become experts—or, indeed, can become misinformed—on their own condition) that physicians should be *seen* to be delivering accurate and relevant information.

In the case of procedures such as ECT which carries potentially very serious side effects, the need for improvement in patient information can be regarded as timely. Given the prevailing variety of claims made about the effectiveness of ECT (from straightforward endorsement for severe depression, to qualified concerns, to outright repudiation of its use as a therapeutic tool), it seems only appropriate that patients are informed of these serious controversies.

Patients should also be informed that there is no explanation as to how ECT works: the declaration of any claim to the contrary—far from informative—is deceptive. More than this, it seems reasonable—given the constraints on testing ECT—that patients should be made aware of the (longest running hypothesis) that ECT may work by inducing placebo responses. In short, if 'the ECT practitioner should be aware that placebo phenomena are commonly at play'[10] and if medical researchers are 'well advised to pay careful attention to placebo phenomena'[10] the medical community is being far from open if it fails to disclose this significant detail to its patients. It is significant in this context that the American Medical Association guidelines prohibit the use of placebos unless patients are informed: 'the use of placebos without the patient's knowledge may undermine trust' and 'compromise the patient-physician relationship'.[39] The claim that placebo use threatens trust and patient autonomy is no less significant when it is 'merely' hypothesised by the scientific community. Arguably this information is even more relevant and significant given that: (a) the procedure is not yet medically explicable and (b) it carries risks. Once again, that patients should be given adequate and relevant information to reach a treatment decision—and that the medical community should be *seen* to provide that information—is especially important given the history of ECT and its use on the most vulnerable of patients. In addition, even if ECT is placebogenic and patients are informed of this *possibility*, this may not curb any possible placebo effects of that treatment (though, of course, that is an empirical matter). One recent study has shown that it may be possible to inform patients that they are receiving a placebo and for placebo responses to be elicited without deception:[11] whether this could be achieved in the case of ECT remains to be seen. It should also be pointed out that these recommendations with regard to ECT also apply to the prescription of antidepressants: there is evidence that antidepressants are not more effective than placebos, and the mechanism of action of antidepressants is still not known.[40]

In summary, the failure to reflect the full current status of theories and medical knowledge in critical clinical encounters can be considered a deception. The lack of honesty with regard to the standing of medical knowledge with regard to ECT left one patient to recount, 'I was to feel like an involuntary game piece in the centre of a quasiscientific [...] debate… I felt that I was being mocked by science'.[18] It may be that an authoritative candour—far from undermining medical authority—builds a more trustworthy patient–physician relationship. Medicine needs to be less coy about the standing of its research if it is to respect patient autonomy and patient capacity to make treatment decisions.

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