CT: Dangerous on Either Side of the Pond

April 5, 2021 John Read, PhD, Sarah Hancock, MS, CRC, Sue Cunliffe, MBchB, RCPCH Psychiatric Times, Vol 38, Issue 4, Volume 04,

No one has precise data about how many Americans receive ECT each year, let alone how many treatments each patients receives or how closely providers space treatments. This is a troubling dilemma, according to the authors.

CLINICAL REFLECTIONS: POINT/COUNTERPOINT

Although electroconvulsive therapy (ECT) is still used on about a million individuals annually, a recent review found "large variation between continents, countries and regions in utilization, rates and clinical practice." For instance, there is a 47-fold <u>difference</u> in usage between the highest and lowest utilizations regions of England.²

In June 2020, this article's first author published his fifth review of the ECT literature since 2010.^{3,4} The most <u>recent review</u>⁴ evaluated the quality of 5 meta-analyses that claimed ECT was effective and safe, as well as the quality of the placebo-controlled studies that had been cited by the meta-analyses. (In these studies, placebo included the general anesthetic without the electric shock.) There have only been 11 placebo-controlled studies of ECT for depression, all of which were conducted before 1986.

POINT/COUNTERPOINT

INTRODUCTION

<u>Electroconvulsive Therapy: Obsolete and Dangerous or Still Just Misunderstood?</u> Horacio M. Capote, MD

The 5 meta-analyses often cited by critics, which included between 1 and 7 of the 11 studies, paid little or no attention to the studies' multiple limitations (**Table**).³

The reviewers concluded that:3

The quality of most SECT-ECT studies is so poor that the meta-analyses were wrong to conclude anything about efficacy, either during or beyond the treatment period . . . Given the high risk of permanent memory loss and the small mortality risk, this longstanding failure to determine whether or not ECT works means that its use should be immediately suspended until a series of well designed, randomized, placebo controlled studies have investigated whether there really are any significant benefits against which the proven significant risks can be weighed.

Table. Issues With the 11 Placebo-Controlled ECT Studies Depression³

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Number of studies that describe their process of randomization	4
Number that are convincingly double-blind	0
Number that selectively report only some of their findings	5
Number that include patients' assessments	4
Number that assess patient quality of life	0
Average number of individuals in the studies	37
Number (out of 11) that found ECT superior to simulated ECT (SECT) at the end of treatment	4
Number that found no difference between ECT and SECT	5
Number that found mixed results	2
Number finding that ECT beat placebo beyond the end of the treatment period	0

Table. Issues With the 11 Placebo-Controlled ECT Studies for Depression³

The review's conclusion that there is no evidence ECT prevents suicide, as often claimed, has been unequivocally confirmed by a study of 14,810 patients who received ECT and 58,369 controls.⁵ Patients in the ECT group were 16 times more likely to attempt suicide over 12 months than the non-ECT patients. Even after controlling for a range of mediating variables, the ECT patients were still 1.3 times more likely to die by suicide (not a statistically significant difference).

The exact incidence of brain damage remains unknown. If brain damage is defined as memory loss persisting at least 6 months after the last ECT, findings range from 12% to 55%.^{6,7} This damage is more common in women and older individuals,⁵ and these groups receive ECT disproportionately.^{2,8} While there are many accounts of devastated

lives on social media, examples in the published scientific literature are less common. One example states:

With each shock treatment, I felt more and more of myself slipping away. I couldn't remember things, particularly the immediate past, but eventually even the more distant past had been erased. I was frightened by this. I thought, 'if I don't know what I've done or where or I've been, then who am I? A person's memories are her identity. Take them away, and you take away her sense of self.'

Advocates of ECT treatment deny it causes brain damage, although a manufacturer of ECT machines includes "permanent brain damage" as a risk. 10,11 Others acknowledge memory loss but blame the depression, not the electricity, even after a review concluded that "There is no evidence of a correlation between impaired memory/cognition after ECT and impaired mood, much less a causal relationship," 12 a conclusion subsequently confirmed in a study by ECT advocate Harold Sackeim, PhD.6

The class action lawsuit currently being prepared in the United Kingdom (UK) is focused not on the memory loss and brain damage per se, but on the failure of psychiatrists to <u>inform</u> patients of that risk.¹³

The risk of death is greater than 1 per 10,000 patients noted by organizations like the American Psychiatric Association.^{3,8} The leading cause of death is cardiovascular failure.⁸ A review of 82 studies with more than 100,000 patients, found that 1 in 50 patients experienced "major adverse cardiac events."¹⁴ In addition, there are other mortality risks, which are higher for older individuals in the target age group for ECT, and are associated with general anesthetic procedures.

The review of meta-analyses3 received wide media coverage. Although some psychiatrists attacked the review, some patients feel vindicated by the findings.

The United States

One of the authors (Hancock) has undergone more than 100 ECT procedures in the United States.

Since the first device classification hearing in 1978, the FDA has requested premarket approval (PMA) electroencephalogram studies (and more recently functional magnetic resonance imaging) to justify device reclassification. Despite never having received PMA data for ECT, the FDA <u>convened</u> a closed hearing during 2018 and reclassified ECT devices from higher risk to moderate risk. This reclassification occurred less than 3 months after ECT machine manufacturer Thymatron published its regulatory update, listing "permanent brain damage and permanent memory loss" as <u>risks</u>. 10.11 Having never undergone PMA safety testing, ECT is unstandardized. Each ECT experience (positive or negative) is therefore just anecdotal evidence.

Psychiatrists, who are not required to study the neuropathology of repetitive high electric field strength on brain tissue, are naive to the compounding microstructural

damages only visible with proper staining techniques and under a microscope. Consequently, many psychiatrists are liable to miss the cellular, microvascular, neuronal, and voltage-gated ion channel damage that is invisible on standard brain scans.¹⁶⁻¹⁹

In 82 years of ECT use, the field of psychiatry has not conducted long-term studies of patients to identify ECT's functional impact on quality of life or aging. Modern research in repetitive brain injury sheds light on the realities faced by millions of ECT recipients. Bennet Omalu, MPH, a neuropathologist who identified chronic traumatic encephalopathy in National Football League players, stated that, where they exist, functional injuries resulting from ECT must be considered as both repetitive brain injury and repetitive electrical trauma.²⁰

Unlike standard documentation required to justify insurance reimbursements, Medicare <u>reimburses</u> ECT "providers who failed to report quality data."²¹ In other fields of medicine, if a procedure is not documented with quality data, it is denied. Yet the reimbursement rate for fiscal year 2021 for "providers who fail to report quality data" is more than the <u>reimbursement</u> rate for properly documented ECT in FY 2020.²²

Given ECT's national reimbursement practices, it is unsurprising that the Substance Abuse and Mental Health Services Administration's National Directory of Mental Health Treatment Facilities ECT provider list jumped from 335 clinics in 2018 to 449 in 2020.²³ The 34% increase in US hospitals providing ECT²⁴ since device reclassification may reflect what happens when hospitals identify an unregulated income source.

Regulating ECT is challenging without an accreditation process to monitor providers. No one knows how many Americans receive ECT each year, let alone how many treatments each individual receives or how closely providers space treatments. This is a troubling dilemma considering Thymatron's regulatory update lists the number of treatments received, and closely spaced treatments as 2 of the 7 independent risks, recognized by the APA, as being related to "permanent memory loss or permanent brain damage." ¹⁰

The United Kingdom

The third author of this piece (Cunliffe) has also undergone ECT. She was a doctor until 2005 when she suffered devastating brain damage from ECT. She has improved over the last 15 years, but she reports disabling neuronal fatigue. She can never work again, and she has lost her independence. Nonetheless, Cunliffe feels fortunate, as she is the only ECT patient she knows who received has neurorehabilitation. She has dedicated herself to preventing the distress of others.

After being admitted to the hospital following coercive abuse, Cunliffe was persuaded to undergo 20 sessions of ECT. Her medical notes clearly demonstrate a lack of monitoring. To the contrary, the notes document her complaints about deteriorating memory, speech slowing down, feeling continuously sedated, and having issues with

motor and coordination skills. Instead of reviewing the treatment plan, the dose was increased from 90 millicombs (mCs) to 700 mCs.

Cunliffe spent 10 years researching ECT practice and the UK's ECT Accreditation Service (ECTAS), which is run by the Royal College of Psychiatrists (RCP). She found a 2015 ECTAS patient survey showed that 19% of patients who received ECT treatment were affected by permanent memory loss; however, this figure is never quoted and ECTAS continues to accredit units that are neither offering informed consent nor monitoring for side effects.²⁵ In the UK, units can continue to operate without accreditation and without meeting the minimum ECTAS standards. Cunliffe has spoken publicly about her story, including at one of the famous Maudley debates at the Institute of Psychiatry, proposing the motion "ECT has No Place in Modern Medicine."^{26,27}

According to Cunliffe, the RCP's response to her recent letter outlining the serious flaws in the ECTAS accreditation service shows that they have no intention of improving standards of care or consent. She added that RCP President Adrian James, FRCPsych, MSc, refused to meet with her and other victims.

A UK coalition of 40 ECT survivors and family members, mental health professionals (including psychiatrists), and researchers have <u>written</u> the health minister calling for an independent enquiry into the practice of ECT.²⁸ The call has been endorsed by many members of Parliament, the National Counselling Society, the Association of Clinical Psychologists UK, the Council for Evidence-based Psychiatry, and, importantly, Headway, the brain injury association. The UK's largest mental health charity, Mind, <u>stated</u>²⁹:

At Mind, we back calls for a comprehensive review into the use of ECT, a potentially risky physical treatment that is still used to treat mental health problems in rare cases. We know that some people have found it effective for improving symptoms of mental health problems—particularly depression—when nothing else has worked. However, we still don't know why it works or how effective it is. Some people who have had ECT may have found they experience adverse side effects that are worse than the symptoms of the problem they're trying to treat, including short term or longer term memory loss.

Concluding Thoughts

We recognize that ECT advocates have their patients' best interest at heart. However, an evidence-based approach to psychiatry dictates that this controversial treatment be suspended pending research that meets 21st century standards to determine whether there are any benefits to offset the proven adverse effects in comparison to placebo. At the very least, to comply with the ethical principle of <u>informed consent</u>, the minority of psychiatrists who continue to use ECT must tell potential ECT recipients that: there is no evidence that it is better than placebo beyond the end of the treatment period, there is no evidence that it saves lives, and studies have found that it causes persistent or

permanent memory loss in 12% to 55% of patients, with particularly high rates among women and older individuals.

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