When All Else Fails

The Use of Electroconvulsive Therapy for Conditions Other than Major Depressive Episode

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KEYWORDS

• Electroconvulsive therapy • Indications • Schizophrenia • Bipolar disorder • Mania
• Post-traumatic stress disorder • Catatonia

KEY POINTS

- Draft guidance prepared by the FDA Office of Device Evaluation for the first time specifies a labeled indication for ECT, restricted to major depressive episode, but ECT practitioners may appropriately provide treatment of other "off-label" conditions.
- Limited evidence supports the inclusion of ECT in the treatment guidelines for treatment-resistant schizophrenia, bipolar mania, and mixed states and catatonia.
- Use of ECT in PTSD and Parkinson disease is encouraging; however, the overall body of evidence is insufficient to support use of ECT as a primary intervention in these conditions because of limited research, sample size, and design limitations. However, there is no rationale for foregoing ECT treatment of another primary indication if comorbid with these conditions, because anecdotal evidence suggests there may be symptomatic improvement and no clear evidence for harm.

INTRODUCTION

In 1938, the US Congress passed the Food, Drug and Cosmetic Act, which gave the Food and Drug Administration (FDA) the authority to oversee and ensure the safety of products meant for human consumption. That same year, the Italians, Ugo Cerletti and

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Lucio Bini, collaborated to develop electroconvulsive therapy (ECT). In 1976, the Dalkon Shield intrauterine device injured at least 900,000 women in the United States, which aided passage of the Medical Device Regulation Act bringing medical devices under the purview of the FDA. Accordingly, ECT was afforded "grandfather" status and classified as a class III (highest risk) device until 2015 when the FDA Office of Device Management proposed new rules for the reclassification of ECT devices as class II (intermediate risk) in recognition of the large body of evidence with regard to its safety.[1] The draft guidance prepared by the FDA Office of Device Evaluation for the first time specified a labeled indication for ECT, restricted to major depressive episode associated with unipolar or bipolar disorder, and for those "patients 18 years of age and older who are treatment-resistant, or who require a rapid response due to the severity of their psychiatric or medical condition." The guidance identifies several populations for which there is "Lack of evidence for efficacy or safety", including, schizophrenia, schizophreniform disorder, schizoaffective disorder, and bipolar mania or mixed states."[2]

Although product labeling is an important mechanism for promoting safe and effective products, the FDA does not define scope of practice. It is therefore understood that physicians may prescribe treatments that are off-label in accordance with professional judgment. This practice is widespread and generally accepted. A recent survey indicated that in a group of commonly used medications in an office-based practice, 21% were for an off-label use, although of concern was the survey's judgment that 73% of those medications had poor or no scientific support for the stated indication.[3] Given the high frequency of treatment resistance across the full spectrum of mental disorders, it is likely that the judicious off-label use of ECT will continue. The impeccable clinician will consult the evidence, document the rationale, and communicate uncertainties as part of the informed consent process.

In this review, we examine certain conditions that are considered off-label indications for ECT under the proposed FDA reclassification, namely schizophrenia, bipolar mania, catatonia, Parkinson disease (PD), and post-traumatic stress disorder (PTSD). We weigh the published evidence to address two main questions: whether the evidence supports the use of ECT, and what recommendations may be offered as to how ECT should be used.

SCHIZOPHRENIA

Among the off-label indications for ECT, schizophrenia emerges as the most time-honored, has the largest empirical basis, and correspondingly greater inclusion in published treatment guidelines. However, there remain sufficient criticisms regarding the evidence base to give pause to clinicians and those who define the coverage policy for national health services and private insurance. The Schizophrenia Patient Outcomes Research Team: Updated Treatment Recommendations make no mention of ECT.[4] In the most recent versions of World Federation of Societies of Biological Psychiatry Guidelines, ECT achieved a low-ranking recommendation as a treatment option, reserved for treatment-resistant schizophrenia as an add-on to antipsychotic treatment and for schizophrenia with catatonic features.[5] The United Kingdom National Institute for Health and Care Excellence guideline on the use of ECT[6] concluded that there was insufficient evidence to endorse the general use of ECT in the management of schizophrenia but did allow that ECT might be effective in acute episodes of schizophrenia with catatonic features, might reduce the likelihood of relapses, and that the combination of ECT and pharmacotherapy might be more effective than pharmacotherapy alone.