Does Bilateral ECT Cause Persistent Cognitive Impairment?

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The December 22, 2006, Web journal Medical News Today features on its front page a limited and sensationalistic account1 of a recent research report from the Columbia group on the long-term cognitive effects of electroconvulsive therapy (ECT) as administered in a group of community hospitals.

The Medical News Today piece will be discussed elsewhere in this issue—my task here is to review the article of Sackeim et al2 for the readers of this journal, some of whom might not have the time to read it closely enough to determine whether its conclusions could be relied on.

Sackeim et al2 started by noting that “there has never been a large-scale, prospective study of the cognitive effects of electroconvulsive therapy” and proceeded to describe their own study as “prospective” and “naturalistic” without revealing whether it had actually been planned or was part of a routine data collection protocol in place for all ECT patients. This is not a trivial point as most prospective studies are planned, and it is specifically the planning that provides much of the value of prospective trials.

Planned or unplanned, the study data were collected at 7 different New York City community-based facilities by a “clinical outcomes coordinator” assigned to each site who collected all research information. Both inpatients and outpatients were included, all satisfying Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition criteria for major depressive disorder or schizoaffective disorder, depressed.

The ECT method was “doctor’s choice” throughout, with no limits placed either on coadministration of psychotropic drugs during or after the ECT course or on administration of additional ECTs during the 6-month follow-up interval.

Assignment to ECT treatment method (eg, pulse unilateral, pulse bilateral, sine bilateral) was nonrandom, and patients could receive a mix of up to 3 different methods during and after their initial treatment course.

There was no untreated or drug-treated depressive control group, only an age-matched “comparison group” of never-ill normal patients.

Unblinded “outcomes evaluators” (presumably the same persons as the “clinical outcomes coordinators” who were described as collecting all data) performed all the patient screening, clinical assessments, cognitive assessments, and comparison group cognitive assessments and attended all ECT sessions to record the ECT treatment data.

How might the conclusions of the article—the main one of which is that bilateral ECT caused cognitive deficits that were detectable 6 months after a course of ECT—have been affected by the methodological deficiencies outlined?

Nonrandom assignment of patients to treatment methods, the absence of an untreated or drug-treated depressive control group, ad libitum coadministration of psychotropic drugs throughout, and administration of additional ECTs during the follow-up interval all combined make it impossible to tell whether the 6-month cognitive deficits reported were the result of ECT, the natural course of depressive disorder, sampling bias, or other confound.
Moreover, the enormous potential bias introduced by having nonblinded evaluators perform all the pre-ECT, post-ECT, and 6-month follow-up clinical and cognitive testing, while collecting all the ECT treatment data during each treatment, is simply immeasurable. Could there not have been a single evaluator at any of the 7 sites whose ratings were colored by a privately held belief that bilateral ECT could cause persistent cognitive deficits at 6 months?

One or two such flaws in a piece of research with such important ramifications would generally preclude acceptance of an article in a peer-reviewed journal, and it is therefore striking that the only methodological limitation of their study that the authors noted in their discussion was the fact that treatment differences were not randomized.

This is especially puzzling because, in an earlier article based on the same community hospital patient sample, the same authors observed that the “doctor’s choice” remission rates obtained were only half as good as expected from the literature and attributed this in large part to contamination of the sample with substantial numbers of depressives with comorbid personality disorders and schizoaffective disorder. The authors laid the blame for the poor outcomes obtained squarely on the “doctor’s choice” treatment providers, who routinely declared patients to be symptom-free after ECT when, in fact, they had significant residual symptoms, hardly a suitable setting from which to draw far-reaching conclusions about the cognitive effects of ECT.

An equally puzzling feature of the study was the inclusion for analysis of patients who had received sine-wave ECT, a method that has been recognized as obsolete since 1982, when it was first banned by the British government’s National Health Service; other governments soon followed. Although Sackeim et al. did mention that 2 patients received sine-wave unilateral ECT, they nowhere revealed how many patients received sine-wave bilateral ECT, a group that certainly should have been excluded from the outset. Had they done so, they would have been able to conduct a straightforward analysis of the 6-month cognitive effects of ECT in a pure sample of pulse-bilateral patients (albeit without a suitable no-ECT control group), which is surely the group of primary interest. Thus, it remains unclear whether, without inclusion of the sine-wave patients, their bilateral sample was sufficiently large to provide the requisite power to show significant cognitive impairment at 6 months.

The authors might perhaps respond that their sophisticated statistical methods such as multivariate analyses of covariance allowed them to partial out all these potential confounds, but if such analyses were all that were required to correct the multiform undesirable effects of serious methodological flaws, why would so much money and time be spent each year to insure the conduct of planned, prospective, random-assignment, double-blind trials, which are the gold standard of all research? The answer is that such trials—and only such trials—are capable of providing the facts that are needed for a valid and reliable assessment of medical treatments.

REFERENCES