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The Sham ECT Literature: Implications for Consent to ECT

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The author reviewed the placebo-controlled literature on electroconvulsive therapy (ECT) for depression. No study demonstrated a significant difference between real and placebo (sham) ECT at 1 month posttreatment. Many studies failed to find a difference between real and sham ECT even during the period of treatment. Claims in textbooks and review articles that ECT is effective are not consistent with the published data. A large, properly designed study of real versus sham ECT should be undertaken. In the absence of such a study, consent forms for ECT should include statements that there is no controlled evidence demonstrating any benefit from ECT at 1 month posttreatment. Consent forms should also state that real ECT is only marginally more effective than placebo.

Keywords: electroconvulsive therapy; sham ECT; treatment outcome

Electroconvulsive therapy (ECT) has been evaluated in randomized, prospective, double-blind, placebo-controlled trials. These studies vary in methodology but all involve the administration of real ECT versus sham ECT under double-blind conditions. In the sham ECT condition, the patients receive a general anesthetic, are hooked up to the ECT machine, and the button is pushed, but no current is delivered. The patients have no way of knowing whether real or sham ECT was delivered. The evaluations of the patients' responses using standardized measures of depression are done by psychiatrists who do not know whether a given individual received real or sham ECT.

The sham ECT studies provide definitive evidence that real ECT is no more effective than sham ECT. The cost-benefit of ECT is therefore negative. The negative side of the cost-benefit analysis is due to deaths, cardiovascular complications, and memory and cognitive impairment caused by ECT (Read, 2004).

THE BENEFIT OF ECT

Endorsement of the Efficacy of ECT in Psychiatry

Although the sham ECT literature proves that ECT is no more effective than placebo, except during the time the treatment is being administered, ECT is widely regarded as highly effective in psychiatry. For instance, in a chapter on ECT in a textbook of psychiatry, Rudorfer, Henry, and Sackeim (1997) state that, "The evidence supporting the efficacy of ECT in depression is overwhelming . . . Janicak and colleagues conducted a meta-analysis of ECT comparison studies in depression. Their results were clear-cut: ECT was found to have efficacy that was superior to all comparison groups, being 41% more effective than

placebo, 32% more effective than sham ECT . . . the extraordinary efficacy of ECT is now well established."

This statement by Rudorfer, Henry, and Sackeim is contradicted and disproven by a study by Sackeim et al. (2001), that is, by the authors' own data, and by the data in the sham ECT literature. In the study by Sackeim et al. (2001), 316 subjects with unipolar major depression were treated with ECT; of these, 290 completed the ECT phase of the study. The response rate to ECT among these 290 subjects was 54.8%, where response was defined as a 60% reduction in Hamilton Rating Scale for Depression (HAM-D) scores. This is not significantly different from the 51% response rate to antidepressant medication noted in a meta-analysis of drug trials by Walsh, Seidman, Sysko, and Gould (2002).

Of the 159 subjects in Sackeim et al. (2001) who remitted in response to ECT, 84 were then randomized to placebo ($N = 29$), nortriptyline ($N = 27$), or nortriptyline plus lithium ($N = 28$). Of the group on placebo, 4 withdrew, 21 relapsed and 4 maintained their remission; of the group on nortriptyline, 2 withdrew, 15 relapsed and 10 maintained their remission; and of the group on nortriptyline plus lithium, 5 withdrew, 9 relapsed and 14 maintained their remission. Thus, of the original 316 subjects started on ECT, only 28 (9.7%) maintained their remission throughout the 24 weeks of the study. These data refute the statement by Rudorfer et al. (1997) that ECT is extraordinarily effective.

Despite the data in the sham ECT literature, the view that ECT is a highly effective treatment for depression continues to be endorsed widely in the psychiatric literature. For instance, the authors of a recent study (Dombrovski et al., 2005) opened their paper with the statement that, "Electroconvulsive therapy (ECT) is the most effective biological treatment for major depression." Yet, the authors of this study reported that of 328 patients scoring 21 or higher on the HAM-D, only 55.8% went into remission after an average of 11.2 ECT treatments.

It is often asserted that ECT is especially indicated for severe depression. However, in a recent study of 73 patients given ECT (Kho, Zwinderman, & Blansjaar, 2005), the remission rate, defined as a 60% or greater reduction in baseline HAM-D score, was 65.7% for participants with baseline scores above 25, and 67.6% for participants with baseline scores below 25. The claim that ECT is particularly superior to medication or cognitive therapy in severe cases is also not supported by a body of adequately designed, replicated data.

I will now review the sham ECT studies, a review article by Janicak et al. (1985), and a recent report of the UK ECT Review Group (2003), in order to demonstrate that: (a) ECT is no more effective than placebo, except during the period of time the treatment is being administered; (b) even during the time it is being administered, real ECT is only marginally superior to placebo; and (c) widespread claims over the past 2 decades that ECT is highly effective are inconsistent with the data.

THE SHAM ECT STUDIES

The following are all the sham ECT studies I could find that meet criteria for the highest, most conclusive level of evidence in medicine: randomized, prospective, double-blind, placebo-controlled trials. It is an undisputed principal of evidence-based medicine that such trials provide definitive evidence of the effectiveness, safety and cost-benefit of a medical treatment.

Brandon et al., *British Medical Journal*, 1984

In this study, 53 patients received real ECT and 42 received sham ECT on a double-blind, prospective, randomized basis. All subjects had a diagnosis of depression. There were no differences between the real and sham ECT groups in scores on the Hamilton Depression Rating Scale (HAM-D) at the beginning of the study or at weeks 12 and 28. The authors focused on the significantly lower HAM-D scores at 2 and 4 weeks but these occurred during the treatment when the patients with real ECT would have been confused and disoriented.

Johnstone et al., *Lancet*, 1980

In this study, 70 depressed patients were randomly assigned to real or sham ECT on a prospective, double-blind basis. There were no differences in HAM-D scores between the two groups at the beginning of the study or at 1 and 6 months. There was a significantly lower HAM-D score in the real ECT group at weeks 2 and 3 while the treatment was being administered.

Gregory, Shawcross, & Gill, *British Journal of Psychiatry*, 1985

In this study, 69 depressed patients were randomly assigned to unilateral, bilateral or sham ECT on a prospective, double-blind basis. The authors discussed at length the significant differences between groups during the course of the treatment: bilateral and unilateral ECT did not differ from each other, and both were superior to sham ECT. However, there were no differences between the three groups on the HAM-D at 1, 3 and 6 months after the end of treatment.

Freeman, Basson, & Crighton, *Lancet*, 1978

In this study, 40 depressed patients were randomly assigned to real (N = 20) or sham ECT (N = 20) on a prospective, double-blind basis. There were no significant differences in HAM-D scores between the two groups at the end of treatment, but the real ECT patients had significantly lower scores during the treatment. Out of the 40 patients, 36 (90%) were rated as "substantially improved."

Brill et al., *Archives of Neurology and Psychiatry*, 1959

In this study, 97 subjects were randomly assigned to receive real unmodified ECT, real ECT plus succinylcholine, real ECT plus thiopental, sham ECT plus thiopental or sham ECT plus nitrous oxide. All patients lost consciousness and were unaware of which treatment they received. Patients were a mixture of people with schizophrenia (N = 60) and depression (N = 30). There were no statistically significant differences between the groups on the main study measure, the Lorr Psychiatric Rating Scale, which measures percentage improvement from baseline.

McDonald, Perkins, Marjerrison, & Podilsky, *American Journal of Psychiatry*, 1966

In this study, 30 depressed subjects were randomly assigned to one of four groups: amitriptyline (N = 10); real ECT (N = 12); placebo medication (N = 4); and sham ECT (N = 4). The two control groups were combined in the analysis of the outcome measures (N = 8).

The retest on the study measures was done only once, at 1 month after the beginning of treatment. There were no differences between the three groups (real ECT; amitriptyline; combined controls) on nurses' ratings of improvement or on Bender-Gestalt drawings. The two treatment groups were equal to each other and both were superior to controls on a psychiatrists' rating of improvement, a depression rating scale, and subscales of the MMPI for depression and psychasthenia.

Due to the small number of subjects ($N = 4$ for sham ECT) and the failure to retest subjects at 1, 2 or more months posttreatment, the results of this study provide little support for the hypothesis that real ECT is more effective than sham ECT, except during the period of time when the treatment is being administered.

Ulett, Smith, & Glesser, *American Journal of Psychiatry*, 1956

In this study, 84 patients were assigned to receive real ECT, photoconvulsive therapy, subthreshold photoconvulsive therapy, or thiopental-induced sleep. There were 21 subjects in each group. Photoconvulsive therapy was a technique in which a seizure was induced by repeated light stimulation combined with the drug hexazol, which reduced the seizure threshold. There were 48 subjects with a "schizophrenic reaction" or an "involutional psychotic reaction," 8 with manic-depression, and 28 with a "psychotic depressive reaction" or "psychoneurotic depressive reaction."

At the end of treatment, the mean improvement on the Malamud Psychiatric Rating Scale was 30.7% for photoconvulsive therapy, 26.8% for ECT, 15.6% for subthreshold photoconvulsive therapy and 15.0% for thiopental-induced sleep. No statistical analyses were conducted.

At 3-month follow-up, the percentage of subjects rated as socially recovered was 57.1% for photoconvulsive therapy, 28.6% for ECT, 4.8% for subthreshold photoconvulsive therapy and 23.8% for thiopental-induced sleep. This means that there was no difference between real ECT and a barbiturate-induced sleep. At 6 months, the percentages rated as socially recovered were 57.1% for photoconvulsive therapy, 19.0% for ECT, 14.3% for subthreshold photoconvulsive therapy, and 19.0% for thiopental-induced sleep.

This study suffers from inclusion of schizophrenic patients, and failure to repeat the main study rating scale at 3 and 6 months. The data show no difference between groups at 3 and 6 months.

Fahy, Imlah, & Harrington, *Journal of Neuropsychiatry*, 1963

In this study, 60 depressed patients were randomly assigned to real ECT, imipramine, or thiopentone sleep. There were 20 subjects in each group. Ratings were made by blind raters at the end of 3 weeks of treatment. Two sets of ratings were reported: staff ratings and doctor ratings. There were no significant differences between the groups on either set of ratings.

Lambourn & Gill, *British Journal of Psychiatry*, 1978

In this study, 16 depressed patients received real ECT and 16 received sham ECT on a randomized basis. After six treatments, the average HAM-D score in the real ECT group was 24, and in the sham ECT group it was 31. After a further month, the average HAM-D score in the real ECT group was 16 and in the sham ECT group it was 12.6.

West, *British Medical Journal*, 1981

In this study, 11 depressed subjects received real ECT and 11 subjects received sham ECT in a double-blind, randomized, prospective format. Two treatments per week were administered for 3 weeks, then subjects could be crossed over to the other treatment on a double-blind basis, "if judged therapeutically desirable." Ratings were done at baseline, at weeks 1, 2 and 3 and then 5 days after the sixth treatment.

The real and sham ECT groups did not differ at baseline but the real ECT group responded much better on a global rating by a psychiatrist, a global rating by nurses and the Beck Depression Inventory. Of the 11 subjects receiving sham ECT, 10 were crossed over to real ECT on a double-blind basis while none of the real ECT subjects were crossed over to sham ECT. Among the ten crossed-over subjects, the average Beck score dropped from 21.1 to 11.9 during 3 weeks of real ECT.

Harris & Robin, *Journal of Mental Science*, 1960

This study involved 4 subjects who received real ECT and 4 who received sham ECT. Two of the real ECT subjects showed slight improvement and two showed great improvement on a nonblind global assessment by clinicians. Three of the sham ECT subjects showed no change and one showed slight improvement according to the nonblind raters. These numbers are too small to have any clinical or statistical significance.

Wilson, Vernon, Guin, & Sandifer, *Journal of Neuropsychiatry*, 1963

In this study, 6 subjects received real ECT and 6 received sham ECT. In addition, 6 received real ECT plus placebo and 4 received real ECT plus imipramine. The average baseline and end-of-treatment scores were not given, but judging by graphs for the individual subjects, the average baseline HAM-D score for the real ECT group was about 29 and for the sham ECT group about 28–29. Average HAM-D score reductions over 5 weeks were 22.3 for real ECT and 10.5 for sham ECT. Although no statistical analysis was done and the number of subjects was small, this appears to be a clinically significant difference. The authors concluded with a statement that the sham ECT "group is too small to estimate what percentage of similar subjects improve without specific electrical and chemical treatments, but certainly some do."

These are all the sham ECT studies I could locate. They uniformly demonstrate that real ECT is no more effective than sham ECT, except during the period of time when the treatment is being administered. This is also the time period when recipients show increased delta waves and decreased alpha and beta waves on electroencephalogram (Weiner, Rogers, Davidson, & Kahn, 1986), and impairment of cognition and orientation (Rudorfer et al., 1997).

A REVIEW ARTICLE BY JANICAK ET AL., *AMERICAN JOURNAL OF PSYCHIATRY*, 1985

Janicak et al. (1985) reviewed the sham ECT literature and tabulated the results from Ulett, Brill, Harris, Fahy, Lambourn, and West in a table. Janicak's review represents itself as a review of the efficacy of ECT for depression. The numbers in Janicak's table do not

match the data in the original studies. Janicak concluded that the overall efficacy of real ECT in these studies was 77.8% compared to 27.6% for sham ECT. However, Janicak misreported the data in the original studies. Errors in the Janicak review include: the number of subjects is incorrect; the number categorized as responders is incorrect or cannot in fact be inferred from the published data; and the fact that psychotic subjects were used in the studies is not mentioned.

Ulett

According to Janicak, the Ulett study involved 43 subjects receiving real ECT and 40 receiving sham ECT. In fact, 21 subjects received electrically induced ECT, 21 received photoconvulsive ECT, 21 received subthreshold photoconvulsive ECT, and 21 received thiopental sleep. Photoconvulsive ECT was more effective than electrically induced ECT.

According to Janicak, 28 of the 43 real ECT subjects were responders while only 14 of the sham ECT subjects were responders. Janicak lumped together the electrical and photoconvulsive patients to support a conclusion about ECT, which is unscientific in itself.

In addition, the data in the original study were not divided into responders and nonresponders; Janicak calculated these results from the ratings in the study. The categories reported in the original study were: recovered; marked improvement; improved; slight improvement; and no change or worse.

If the real and photoconvulsive ECT groups are combined for $N = 42$ and the subthreshold photoconvulsive and thiopentone groups are combined for an $N = 42$, then 28 subjects given real ECT were improved or better, while 15 of the sham ECT subjects were improved or better. Janicak's review describes ECT for treatment of depression; the authors do not mention that 48 of Ulett's subjects had psychoses.

Brill

According to Janicak, in this study 18 subjects received real ECT and 8 received sham ECT: 12 real ECT subjects responded compared to 2 sham ECT subjects. In fact, 59 subjects received real ECT and 39 received sham ECT. The data were reported as percentage of improvement and there is no plausible way to convert them to dichotomous categories of responder and nonresponder. Also, 38 subjects receiving real ECT had schizophrenia.

Harris

Janicak grouped nonblind global assessments of no change or slight improvement into a category of nonresponder, and categorized subjects showing great improvement as responders. This is reasonable and he had the number of subjects correct.

Fahy

According to Janicak, in the Fahy study, 17 subjects received real ECT, of whom 12 were responders, while 17 subjects received sham ECT, of whom 8 were responders. In fact, 20 subjects were randomized to receive real ECT, 20 to receive imipramine and 20 to receive thiopentone. There were no significant differences between groups. At the end of the trial, 17 real ECT subjects and 17 sham ECT remained in the study: 12 real ECT subjects were rated as improved, or recovered or minimal symptoms only, compared to 8 sham ECT subjects. In this study, Janicak had the numbers right, but did not comment on the lack of statistical significance.

Lambourn

According to Janicak, in this study 16 subjects received real ECT and 16 subjects received sham ECT, with 8 responders in each group. In fact the sham ECT group showed greater improvement on the HAM-D. HAM-D scores were also reported as 1%–33% improvement, 34%–66% improvement, and 67%–100% improvement. According to these ratings, 6 subjects in each group improved 67%–100%. The total improving 34%–100% was 11 in the real ECT group and 11 in the sham ECT group. Although Janicak was correct that the groups had equal numbers of responders, the absolute numbers are wrong in the review article.

West

According to Janicak, in this study 11 subjects received real ECT, of whom all 11 were responders, while 11 subjects received sham ECT, of whom only 1 was a responder. The numbers of subjects are correct. The data were in fact reported as average scores on three different measures; subjects were not divided into responders and nonresponders by West. Janicak classified subjects as responders if they were crossed over and then reported that 11 of 11 real ECT subjects were responders compared to 0 of 11 sham ECT subjects. This is a fairly reasonable extrapolation from the crossover data but it may not be valid. Since subjects were crossed over "if judged therapeutically desirable," some of them may have been partial responders. Nevertheless, the West study supports the overall conclusion that real ECT causes a greater reduction in depression than sham ECT during the period of time the treatment is being administered, and for a short time after the end of treatment.

The randomized, prospective, double-blind, placebo-controlled literature on the efficacy of ECT is consistent and conclusive: There is no difference between real and sham ECT except during the period of time the treatment is being administered. For instance, West (1981) noted that, "the relapse rate after electric convulsion therapy or after six weeks' treatment with an antidepressant remains high."

The review article by Janicak concludes that the efficacy of real ECT is 77.8% compared to 27.6% for sham ECT. This conclusion is based on a review of six sham ECT studies in which, according to Janicak, 73 of 109 subjects responded to real ECT, compared to 3 of 28 subjects who responded to sham ECT. These numbers in fact yield response rates of 66.9% for real ECT and 10.7% for sham ECT.

Janicak's meta-analytic conclusion in the text of the review article (77.8% vs. 27.6%) doesn't match the data in his own table (66.9% vs. 10.7%). Further, the data in the Janicak table do not match the data in the original studies. Therefore Janicak's conclusion is not scientifically sound. It is directly contradicted by the data in the original studies.

Dichotomous categories of responder and nonresponder cannot be derived from the Brill study, therefore it can be excluded. Dichotomized categories can be derived from the crossover rates in the West study, but the validity of equating crossover with nonresponder status is uncertain. The studies by Harris, Ulett, Fahy, Lambourn, and Harris yield a total of 79 subjects receiving real ECT, of whom 53 responded (67.1%) and 79 subjects receiving sham ECT, of whom 34 (43.1%) responded. This is a much more modest finding than the 77.8% versus 27.6% reported by Janicak.

The Janicak responder analysis appears to support the conclusion that real ECT is superior to sham ECT. This is not true for several reasons. First, in studies using a valid and reliable measure of depression, the HAM-D, there is consistently no difference between groups, except during the period of time the treatment is being administered. Janicak's responder

status is derived from ratings at the end of treatment, rather than at 1-, 3-, and 6-month follow-ups, at which time no study has found a difference between groups on any measures. Third, several of the studies included psychotic subjects who were not analyzed separately, therefore no clear conclusions about the efficacy of ECT for depression can be drawn from them.

A REVIEW ARTICLE BY THE UK ECT REVIEW GROUP, *THE LANCET*, 2003

The UK ECT Review Group (2003) concluded in a review of the Wilson et al. (1963), West (1981), Lambourn and Gill (1978), Freeman et al. (1978), Gregory et al. (1985), and Johnstone et al. (1980) sham ECT studies that, "Real ECT was significantly more effective than simulated ECT. This result translates into a mean difference in the Hamilton depression rating score (HRDS) of 9.7 (95% CI 5.7 to 13.5) in favour of real ECT. In only one trial were depression ratings scores reported at 6 months after the end of ECT, and a nonsignificant two-point difference in final HDRS was noted (95% CI -2.7–6.7) in favour of the simulated group."

Like the Janicak et al. (1985) review, the UK ECT Review group's findings 2 decades later are not consistent with the data in the original studies. The view that ECT is highly effective continues to be endorsed in review articles up to the present (American Psychiatric Association, 2001; Husain et al., 2004; Kho, Van Vreeswijk, Simpson, & Zwinderman, 2003; Pagnin, De Queiroz, Pini, & Cassano, 2004; van der Wurff, Stek, Hoogendijk, & Beekman, 2003; Wijeratne, Halliday, & Lindon, 1999), even though it is contradicted by the data.

Examining the UK ECT Review Group's analysis of the six sham ECT studies they cite as providing HAM-D evidence of the superiority of real ECT, the first problem is that the HAM-D was not administered in West (1981). It can therefore be excluded.

In the remaining five studies, the UK ECT Review Group had the number of subjects correct, but in Johnstone et al. (1980), the number of subjects in each group is not stated. The ECT Review Group did not state what assumption it made concerning the number of subjects in each group. It only cited the fact that 70 subjects were entered, and did not note that only 62 completed the study. I will assume 36 subjects in each group for my analysis.

Wilson et al. (1963) reported only change scores, not baseline and end scores: a reduction of 22.3 (*SD* 1.6) for real ECT and 10.5 (*SD* 5.9) for sham ECT. Freeman et al. (1978) did not state the HAM-D scores but they can be estimated from graphs; baseline of 29 and end-point of 13 for real ECT; and baseline of 28 for sham ECT and end-point of 11 for sham ECT.

Gregory et al. (1985) reported a score reduction of 30.5 for unilateral ECT, 30.5 for bilateral ECT, and 13.9 for sham ECT. I will combine the two real ECT groups for my analysis below. Johnstone et al. (1980) did not report numerical HAM-D scores, but they can be estimated from their graphs: baseline of 55 and end-point of 18 for real ECT, and baseline of 51 and end-point of 17 for sham ECT. Lambourn and Gill (1978) reported a baseline score of 50 and end-point score of 16 for real ECT, and a baseline score of 54 and end-point of 12.6 for sham ECT.

These data yield the following for real ECT: $[(6 \times 22.3) + (20 \times 16) + (46 \times 29.25) + (36 \times 37) + (16 \times 34)] = 3675.3/124 = 29.6$ average HAM-D score reduction. For sham ECT, the findings are: $[(6 \times 10.5) + (20 \times 17) + (23 \times 13.9) + (36 \times 34) + (16 \times 41.4)] =$

2381.4/101 = 23.6 average HAM-D score reduction. Thus the difference between real and sham ECT is 6 points, not 9.7 as reported by the UK ECT Review Group.

In the three studies for which baseline HAM-D scores were reported, the average was 47 for real ECT and 45 for sham ECT, so the randomization appears sound. Averaging the baseline scores, then, if a person starts with a HAM-D score of 46, on average at the end of treatment, his score will be 16 if he got real ECT and 22 if he got sham ECT. Although this may be statistically significant, it is not a robust difference clinically. It does not support the conclusion that ECT is powerful and effective. Only a modest excess cost for real ECT, in terms of morbidity and mortality, would be required to yield an overall negative cost-benefit for real ECT.

THE COSTS OF ECT

The cost side of the cost-benefit equation for ECT was recently reviewed by Read (2004). Read (2004) demonstrates that just as the benefit of ECT is overrated by proponents, so too the cost is minimized. For instance, Rudorfer et al. (1997) state that the risk of serious complications is about 1 in 1,000 patients, while the risk of death is about 1 in 10,000 patients, which is approximately the same as the rate of death from general anesthesia. The data do not conform to these claims: for instance, Frank (1978), in a review of 28 articles on death rates from ECT, reported that there were 90 ECT-related deaths out of 130,216 patients, a rate of one death per 1,447 people. Pippard and Ellam (1981) reported four deaths out of 2,594 patients, a rate of one death per 648.5 persons treated with ECT. Other studies reported ECT-related death rates as high as one patient out of 212 (Breggin, 1979) and one per 298 patients (Strensrud, 1958).

OVERALL CONCLUSIONS

Significant costs of ECT in terms of death, cardiovascular complications, and impairment of memory and cognition are described by ECT advocates (Rudorfer et al., 1997). Since there is no demonstrated benefit from real ECT compared to sham ECT, except during the time the treatment is being administered; since even that difference is modest; and since ECT has associated morbidity and mortality; an adequate study of the effectiveness of ECT should be undertaken by investigators who wish to continue using ECT.

The burden of proof that ECT can be prescribed ethically and rationally lies with its advocates. They should conduct a research study involving a randomized, prospective, double-blind, placebo-controlled design in which the placebo is sham ECT. In such a study, all subjects should meet DSM-IV-TR criteria for unipolar depression and all should score above a standard cutoff of 20 on the HAM-D. Even with this design, it is questionable whether a true double blind is ever possible in sham ECT research, and questionable whether the HAM-D is valid in the real ECT group, due to the cognitive impairment that is universal during the time real ECT is being administered.

Sham and real ECT subjects should be further randomized to receive a selective serotonin reuptake inhibitor (SSRI) or a placebo. The medication arm of the study should be continued for 12 months and subjects should be classified as responders if their HAM-D scores drop by 50%. Average score reductions in each of the four groups (real ECT-SSRI; real ECT-placebo; sham ECT-SSRI; sham ECT-placebo) should also be calculated, as should

relapse rates. About 30% of subjects in the sham ECT-placebo group should be responders, since this is the overall average placebo response rate in antidepressant studies (Walsh, Seidman, Sysko, & Gould, 2002).

ECT can only be administered for a short period of time due to increasing cognitive impairment and disorientation, therefore it is not possible to provide two or three treatments a week as a maintenance treatment. The only possible benefit of ECT compared to antidepressant medication is a more rapid induction of remission, followed by a high rate of relapse in the absence of maintenance medication. Whether this is a true antidepressant effect of ECT or merely an artifact of cognitive and memory impairment could be determined with valid and reliable measures of cognition and memory performance, which should be included in the study.

Repeated electroencephalograms should be taken during the research study. They might demonstrate that the "antidepressant" effect of ECT correlates with the presence of an ECT-induced organic brain syndrome characterized by increased delta waves and decreased alpha and beta waves on electroencephalogram (Weiner et al., 1986), and impairment of cognition and orientation (Strensrud, 1958). Other study measures should be medical in nature, and should include cardiovascular, pulmonary and other complications, and mortality in the two groups throughout the study period. Attempted and completed suicide and rates of rehospitalization should also be monitored.

In the absence of such a study, whatever its outcome, the sham ECT literature supports the conclusions that: real ECT is no more effective than placebo, except during the period of time the ECT is being administered; even that difference is modest; a modest amount of cost is required for the overall cost-benefit of ECT to be negative; and, the effectiveness of ECT is overendorsed repeatedly in the psychiatric literature up to the present.

In the absence of an adequately designed and definitive study of real versus sham ECT, ECT consent forms should be modified to state that there is no demonstrated benefit of ECT beyond the period of time it is being administered, and that the difference between real and sham ECT during treatment is modest. It is difficult to understand how anyone could give meaningful consent to ECT without this information being presented to them.

A review of the ECT literature should be undertaken by the Food and Drug Administration, focusing on the effectiveness, complications, and side effects of ECT. This review should be conducted by independent scientists who are not psychiatrists and who do not have a vested interest in ECT. The Food and Drug Administration should then decide what warnings, if any, should be required for ECT, just as it has for psychiatric medications. ECT should be held to the same regulatory and ethical standards as psychiatric medications. While such a review is pending, and until an adequately designed study such as the one outlined above has been completed, consideration should be given to a moratorium on clinical use of ECT.

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