Informed Consent in the Electroconvulsive Treatment of Geriatric Patients

Stewart B. Levine, MD; Karen Blank, MD; Harold I. Schwartz, MD; and Douglas S. Rait, PhD

The past 15 years have been marked by an increasingly stringent regulatory atmosphere regarding the administration of ECT, leading to delays in treatment and declines in usage. Regulatory changes requiring judicial intervention in clinical decisions are driven by the notion that only the courts can provide adequate due process protections when legal rights and clinical need conflict. We retrospectively reviewed the documentation of the informed consent process for 62 geriatric patients receiving ECT to assess the degree to which clinicians conformed to the spirit of the informed consent doctrine in a state that allows significant clinical discretion in decisions to administer ECT to patients lacking decisional capacity. In the eight cases in which the patient's decisional capacity was questioned, we found appropriate documentation of the patient's failure to comprehend his condition or the proposed treatment, evidence of a high degree of family involvement in decision making, and extensive use of outside consultants to document decisional incapacity and the need for treatment. Evidence of family participation in decision making was present for a high percentage of cases in which decisional capacity was unquestioned. Our review demonstrated high compliance with the procedural safeguards contained in the state regulation and with the spirit of the informed consent doctrine.

Few psychiatric treatments have generated as much controversy as electroconvulsive therapy (ECT).[1] Despite overwhelming evidence of the efficacy and safety of ECT,[2-6] the past 15 years have been marked by an increasingly stringent regulatory atmosphere regarding this treatment.[7,8] As of 1985, 43 jurisdictions had statutes that at least implicitly governed ECT, and 25 states had specific regulations.[8,9] ECT statutes are generally designed to ensure the patient's informed consent and to protect his right to refuse treatment.[1] While there is little controversy over the right of a competent patient to refuse ECT, the question of procedural safeguards for the patient lacking decisional capacity remains at

Dr. Levine is unit chief, Department of Psychiatry, Beth Israel Medical Center and Instructor in psychiatry, Mount Sinai School of Medicine, New York, NY. Dr. Blank is adjunct assistant professor of clinical psychiatry at Mount Sinai School of Medicine, New York, NY. Dr. Schwartz is Director, Department of Psychiatry, Hartford Hospital, Hartford, CT, and associate professor and associate chairman, Department of Psychiatry, University of Connecticut School of Medicine, Farmington, CT. Dr. Rait is director, Family Studies Program, Department of Psychiatry, Beth Israel Medical Center and assistant professor of Psychiatry, Mount Sinai School of Medicine, New York, NY. This study was performed at Beth Israel Medical Center, New York, NY. Address reprint requests to Dr. Levine, Department of Psychiatry, Beth Israel Medical Center, First Avenue and 16th Street, New York, NY 10003.

issue and is the subject of increasingly stringent regulation. Legal theorists have argued that the "intrusive" nature of ECT is such that judicial intervention is necessary to provide adequate protection of the incompetent patient's interests.[9] Central to this conflict is the question of the degree to which psychiatrists can reasonably be expected to protect their patients' rights while providing for their clinical needs.[10]

Must treatment decisions for incompetent patients always be made by the courts, or can they be appropriately made by physicians in conjunction with families? Shifting the focus of clinical decision making to the judicial arena when there is a question of decisional capacity for specific treatment brings attendant risks. The California statute, for example, which requires judicial review for decisionally incapacitated patients as well as a variety of other cumbersome procedures before ECT can be administered, has delayed and discouraged the use of ECT in that state, leading to various clinical complications including death.[11-13] On a nationwide basis there have been delays in treatment and significant declines in ECT usage, resulting in part from regulatory and legislative pressures.[14]

In the state of New York, ECT may be administered to any patient lacking the capacity to give informed consent after obtaining the informed consent of another person authorized to act on the patient's behalf. This is usually a family member, and court authorization or adjudication of incompetency to consent is not required. The decision that the patient lacks capacity is rendered by the "chief of service."[15] When it is not clear that the patient has the capacity to give consent, the law requires the staff to obtain an "independent opinion" of a qualified consultant" not employed by the facility.[15] While the *Rivers v. Katz* decision, rendered by the New York State Court of Appeals in 1986, required judicial review of competency and the need for treatment for patients refusing psychotropic medication,[16] that decision did not specifically refer to ECT. Hence, at the time of this study, an involuntary patient refusing ECT could be treated following a clinical determination of decisional incapacity to consent and with the substituted consent of a family member. We considered a geriatric psychiatry unit, with frequent utilization of ECT, in a state with such a relatively "relaxed" regulation to be an excellent laboratory for the examination of the extent to which clinicians and family members appropriately balance the preservation and protection of the patients rights with the often pressing need to administer ECT.

While it has been well documented that the depressed geriatric population is one for which ECT is often the treatment of choice,[4,5] it is in this population that the capacity to give informed consent is most often in question. Capacity to consent may be impaired as a consequence of depressive disorder, dementing illness, or a host of other medical and psychiatric complications of aging. This problem is not limited to the elderly, as research has demonstrated that many psychiatric patients do not have

the capacity to give consent even to hospitalization.[17] Psychiatric and medical patients are often unable to demonstrate an understanding of treatment or research programs.[18,19] To complicate the issue, decisional capacity determinations may be subtle and complex, and the patient's clinical competency may shift over the course of a single hospitalization.[20] In this study we examined the hypothesis that physicians recognize and appropriately utilize the informed consent doctrine and comply with regulations protecting patients' rights while treating seriously ill geriatric patients with ECT. We retrospectively examined the clinical records of a population of elderly patients who were administered ECT. Recognizing the significant limitations involved in studying informed consent through retrospective chart review, we sought evidence of the documentation of the informed consent process, of family involvement in decision making, and of appropriate review of decisional capacity for patients believed to lack capacity. Regarding nonconsenting patients, we were particularly interested in their clinical characteristics, the circumstances under which they were treated, and the safeguards employed to ensure protection of their rights.

Methods

The study was designed as a retrospective chart review. Charts were examined of all patients who had received ECT in a 1.5 year period from January 1986 through June 1987 on a 26 bed specialized geriatric inpatient unit. The unit is located in a voluntary nonprofit hospital and accepts both voluntary and involuntary patients. Demographic information was recorded regarding each patient's age, sex, race, and marital status. Discharge diagnoses and data regarding past treatments and responses were obtained. Diagnoses were made by the treating physician according to DSM-III criteria. The general medical and psychiatric condition was determined both from a review of daily progress notes and from compilation of data from weekly summary forms (developed and used within our department). These were completed by the treating physicians who rated a list of symptoms on a severity scale of 1 to 5. The patient's condition was defined as life-threatening if concerns about suicidality were above the threshold requiring an order for constant observation or if he or she was refusing nutrition to the point of physical jeopardy or consistently refusing necessary and life sustaining medical treatments such as cardiac medications or insulin.

All records were reviewed for documentation of the indications for ECT and the discharge diagnosis. Assessments of improvement following ECT administration were made by one of the authors (S. L.) after a review of the daily progress notes and the weekly summary forms. This assessment was made after the full course of ECT had been completed. Marked response to treatment was indicated when there had been an improvement in all of the presenting symptoms. Moderate improvement was used to categorize those patients who showed improvement in only some of

their symptoms, but not all. Those patients with little or no change in any of their presenting symptoms were considered to have minimal or no improvement.

Also obtained were the legal status at the time of the first ECT, the source of the consent (when not given by the patient), and documentation of family corroboration of the consent for ECT. The records were studied for documentation of the patient's comprehension of his condition and the proposed treatment.

Results

Sixty-two patients received ECT during the study period of which 17 were male and 45 female. The patients were treated by 17 physicians, including full-time staff, private attendings, and residents. The patients ranged in age from 50 to 89 years (median age 72.5 years). The majority of the patients were white (87.1%, n = 54). Hispanic patients represented 9.7 percent (n = 6) and black patients represented 3.2 percent (n = 2). Married patients represented 45.2 percent (n = 28) of the group, 37.1 percent (n = 23) were widowed, 6.5 percent (n = 4) were divorced, and 11.3 percent (n = 7) were single.

Patient diagnoses were as follows: recurrent major depression without psychotic features 41.9 percent (n = 26), recurrent major depression with psychotic features 29 percent (n = 18), major depression, single episode without psychotic features 8.1 percent (n = 5), organic affective disorder 4.8 percent (n = 3), bipolar disorder mixed with psychotic features 3.2 percent (n = 2), bipolar depressed without psychotic features 3.2 percent (n = 2), and primary degenerative dementia with depression 3.2 percent (n = 2). Other diagnoses, each involving only one patient, were bipolar depressed with psychotic features, major depression single episode with psychotic features, atypical psychosis, and bipolar mixed without psychotic features.

The clinical indications for ECT were determined from the records. Because there were many patients who had several indications documented, the number of indications is greater than the number of patients. Patients who had a prior favorable response to ECT numbered 31 (50%) (the number of prior courses ranged from 1 to 8, with an average of 2.1); patients who failed therapeutic trials of medication for the index illness numbered 29 (46.8%); 18 patients (29%) were intolerant of the medications and, therefore, required discontinuation of the medication; and 10 patients (16.1%) had medical problems that precluded or greatly complicated the use of medication.

At the time of commencing ECT, 74.2 percent (n = 46) of the patients were voluntarily hospitalized, and 25.8 percent (n = 16) were involuntarily hospitalized.

The majority of patients in the study, 87.1 percent (n = 54), consented to ECT. Eight patients (all involuntarily hospitalized) were unwilling or unable to consent. Of these, three patients (4.8%) refused the treatment and five patients (8.1%) were unable to communicate an informed choice. Progress note docu-

mentation indicates that each of the refusals was based on psychotic thinking either about the underlying condition or about the treatment being offered. Of note, two of the patients who initially refused later gave consent after starting ECT with improvement of their conditions. For the purposes of data analysis and discussion, these patients are included in the nonconsenting group.

Examination of the charts of the eight patients who did not consent to ECT did not reveal any differences from consenting patients in gender, ethnicity, age, or marital status. The nonconsenting patients were more often psychotic than those consenting. Psychosis was present in seven of the eight nonconsenters (87.5%), and 22 of 54 (40.7%) of the consenters. Diagnoses of the eight nonconsenting patients were: five recurrent major depressions with psychotic features (62.5%); one bipolar disorder, mixed, with psychotic features (12.5%); one bipolar disorder, depressed with psychotic features (12.5%); and one recurrent major depression without psychotic features (12.5%).

Of the eight nonconsenting patients, all eight met criteria for having life-threatening conditions, as compared with 29.6 percent (16 of 54) consenting patients. A history of prior response to ECT was found in 75 percent (n = 6) of the nonconsenting patients, compared with 48.3 percent (n = 25) of the consenting patients. Fifty percent (n = 4) of the nonconsenting patients refused essential medical treatment, compared with 3.7 percent (n = 2) of the consenting patients. A failure of one or more therapeutic trial(s) of antidepressant medication was found in 50 percent (n = 4) of the nonconsenting patients, while in the consenting group, 46.3 percent (n = 25) had failed such trial(s). Seventy-five percent (n = 6) of the nonconsenting patients suffered from severe nutritional compromise, as compared with 16.7 percent (n = 9) of the consenting patients. In the nonconsenting group, 12.5 percent (n = 1) were intolerant of medication, while 33.3 percent (n = 18) of the consenting group were; 37.5 percent (n = 3) of the nonconsenting patients displayed physically dangerous or suicidal behavior, compared with 7.4% (n = 4) of the consenting patients. Finally, 5.6 percent (n = 3) of the consenting patients had requested a course of ECT.

Of the 54 patients who consented to ECT, 46 had been voluntarily hospitalized and 8 were involuntarily hospitalized.

Review of items relating to the consent process revealed the following: All of the consenting patients signed the consent for ECT form in use at our hospital. In each case a witness signed the form in addition, to verify that the patient had freely consented and signed the form. Twenty-nine percent (15 of 54) of these charts contained specific additional documentation of the patient's comprehension of the risks and benefits of ECT, and eight contained explicit statements regarding the patient's decisional capacity. Of interest is the finding that clinicians tended to obtain family consent regardless of the status of the patient's own consent. Of the

46 voluntary patients who consented to ECT, 26 (56.5%) had documentation of family consent in addition to their own signed consent. Family members involved in the consent process included children 54 percent (n = 14), spouse 35 percent (n = 9), other 7 percent (n = 2), and sibling 4 percent (n = 1). Sixteen (34.8%) had cosignatures by relatives on their consent forms, and 10 (21.7%) had documentation of family agreement in the chart notes. Of the eight involuntarily hospitalized patients who consented to ECT, six had documentation of family consent as well. Of the eight nonconsenting patients, seven (87.5%) had family consent documented. The eighth patient, whose medical condition was deteriorating rapidly, had no family member available to provide substitute consent. In the face of an impending medical emergency, three outside consultants rendered concurring opinions regarding the need for ECT and the patient's lack of capacity to consent to it.

The staff involved the family more often when there was a life threatening condition. In the voluntarily hospitalized, treatment-consenting patients, 16 had documentation of the presence of a life threatening condition; and, of these, 11 charts had cosignatures by relatives (69%). This contrasted with only 5 of 20 (25%) of family cosignatures for patients not considered to have life threatening conditions ($\chi^2 = 5.23$, df = 1, $p = .022$). The presence of psychotic symptoms did not appear to significantly affect the decision to obtain family cosignature ($\chi^2 = 1.49$, df = 1, $p = .22$).

Of the eight nonconsenting patients, all had life threatening illnesses, and each chart contained documentation of the patient's failure to comprehend his or her condition. Prior to commencing treatment, all but one patient (87.5%) had chart documentation of a determination by an outside consultant regarding the patient's decisional incapacity. The remaining patient had a consultation submitted by the unit chief.

The majority of patients showed impressive responses to ECT . Marked improvement was seen in 41.9 percent (n = 26), 45.2 percent (n = 28) showed moderate improvement, while 12.8 percent (n = 8) had minimal or no improvement. All of the nonconsenting patients showed moderate or marked improvement.

Discussion

No retrospective chart review can hope to capture the essence of informed consent. Informed consent is a process, rather than a single event,[21] and as such is not truly "documented" by the mere process of a signed informed consent document.[22] Nevertheless, compelling information about informed consent and clinical decision making around issues that strike a balance between patients' needs and rights can be inferred through the process of chart review.

Our results demonstrate that considerable care was taken in obtaining informed consent for ECT both with patients considered clinically competent and with those whose capacity was in question. This care was especially evidenced by the proportion of patients' families who were involved in the con-

sent process and by the high degree to which the nonconsenting patients were afforded the protection of both family involvement and examination by outside consultants. The clinical determinants of the decision to administer ECT to patients lacking decisional capacity were compelling and argue convincingly that these patients were in need of treatment.

The majority of our geriatric patients (87%) who received ECT gave informed consent themselves for the treatment; 29% of the charts of these consenting patients contained documentation as to the actual content of the informed consent discussion, and 15% contained statements specifically describing the patients as competent regarding their decision process. It is not possible to say how many of the other patients in our sample possessed a thorough, informed understanding of the treatment being offered and how many merely assented and signed the consent form. This absence of corroborating documentation is problematic and probably not uncommon; however, it is balanced by the impressive finding that 59% of the charts reviewed contained evidence of additional consent obtained from a family member (though such additional consent is not required by statute or regulation for competent patients). Indeed, patients are presumed competent until proven otherwise under the law unless there are substantial reasons to suggest otherwise.[22] One could reasonably argue that additional documentation in progress notes is provided only when questions of decisional capacity warrant it. On the other hand, the lack of additional chart documentation in many charts may reflect the clinical practice of accepting, without much scrutiny, the consent of a patient who agrees to a necessary treatment and is in agreement with his physicians. Because he is making a "reasonable decision" with a "good outcome" his consent may be held to a lower standard of competence than if he were to refuse that treatment.[20,23] It is difficult to arrive at conclusions about the quality of a patient's consent without specific descriptors of the informed consent process entered into the chart.

Of note, in *Zinermon v. Burch*[24] the Supreme Court recently confirmed that decisionally incapacitated patients cannot consent to voluntary hospitalization, which requires informed consent. By implication, determinations of capacity to consent must be made prior to accepting the patient's consent. If such a principle were to be extended to treatments such as ECT, evaluations of decisional capacity and documentation of these evaluations would be required in all cases.

An examination of the clinical decision making and procedural safeguards employed for those patients believed to lack decisional capacity is most central to the issue of the degree to which psychiatrists can reasonably balance the protection of patients' rights with the need to provide care. Each of these eight patients had been involuntarily hospitalized. All but one had documentation of consent for ECT from the family, and in the one instance in which family was not available, there was documentation

of consultation from three outside experts on the question of the patient's lack of decisional capacity and need for treatment. All but one chart contained documentation of an outside consultant's review of decisional capacity and the need for treatment, and that chart contained such a review by the unit chief acting as the delegate of the "chief of service." This is evidence of substantial compliance with both the letter and the spirit of New York State's regulations.

The clinical determinants of the decision to treat these clinically incompetent patients, as reviewed above, were compelling. This was indeed the clinical picture of patients very much in need of treatment and likely to benefit from it. It is of note that all eight were judged to have improved either moderately or markedly with this course of ECT treatment.

There were eight patients who were considered to be able to consent to ECT even though they were not hospitalized voluntarily. As voluntariness is an essential component of the informed consent process, this does raise the issue of coercion by virtue of their involuntary status.[22] The involvement of family members in the consent process of 75% of these patients may represent a mitigating factor.

There is no question that the consent process for ECT with geriatric patients should be precise and careful and should be completely documented, as both the APA and an NIMH Panel have recommended.[2,3] The NIMH Panel suggests that because patients who receive ECT are likely to lose their memory of giving consent to treatment and because they are likely to have been ill when doing so, an ongoing vigorous consultation between doctor, patient, and family is necessary. A 1990 APA Task Force also stressed the need for informed consent, suggesting that the content of the consent include a description of the procedure and its indication, the predicted course with and without ECT, a description of reasonable treatment alternatives, a statement of risks and benefits of ECT and alternative treatments, and a statement about the patient's right to refuse.[2] It was recommended that the above information be entered into the patient's chart along with documentation that the patient giving consent was competent to understand and act on it.[2]

Although the present New York regulations allow physician discretion to give ECT to incompetent patients, there are changes afoot. The 1986 *Rivers v. Katz* decision found that the determination of capacity to make a treatment decision regarding psychotropic medication is "uniquely a judicial, not a medical function."[16] As a result, decisions that formerly had been made clinically now require a court hearing. This decision does not apply to ECT at this time, although it appears that an extension of this regulation, requiring judicial approval in ECT cases, may be coming soon.[25] It will be unfortunate if New York State goes the way of more restrictive states and, as a result, renders ECT treatment less accessible to patients in need of treatment.

Conclusion

ECT is an impressively safe and effective treatment for geriatric patients. Our

high rate of response is consistent with that found in other reports.[4] The jurisdiction in which this study was done allows for the timely treatment of patients whose decisional capacity may be in question. The documentation we reviewed demonstrates compliance with the procedural safeguards contained in these regulations although documentation can be improved in many cases. Were the regulations to become more restrictive, we would have to anticipate that treatment would be impeded, as has happened in other states. Given the excellent clinical results reported in our sample and the literature at large, with relatively accessible treatment, there is little room for change but in the direction of poorer patient outcome. This has potentially disastrous implications for the frail, urgently ill geriatric population. It is clear that the judiciary always has a role to play in contested cases. However, in many other cases psychiatrists can balance the patient's clinical needs and rights, providing ECT to decisionally incapacitated patients without judicial intervention.

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