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Multicenter Observational Study of Electroconvulsive Therapy in Japan

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Objectives: The present study is the first large-scale, multicenter survey on modified electroconvulsive therapy (ECT) in Japan. We aimed to comprehend the current implementation status of ECT based on the annual reports of 2016 from 21 facilities that were certified by the Japanese Society of General Hospital Psychiatry as ECT certified facilities and participated in this multicenter observational study.

Methods: We investigated the distributions of diagnosis, gender, and age of patients receiving acute-phase ECT, and the efficacy, safety, and adverse events.

Results: The number of patients receiving acute-phase ECT was 524. According to *International Classification of Diseases*, *10th Revision*, 344 patients (65.6%) were diagnosed with mood disorders (F3), 156 patients (29.8%) were diagnosed with schizophrenia and with schizotypal and delusional disorders (F2), and 151 subjects were male and 334 subjects were female. The mean age of patients was 60.4 years (SD 15.9), and patients 60 years or older accounted for 57.9%. Efficacy did not significantly differ between diagnoses, nor between genders. However, the efficacy rate was significantly higher in elderly patients. In acute-phase ECT, 4 severe adverse events occurred.

Conclusions: Our multicenter study confirmed that F3 (mood disorders) was the most common indication for ECT at 66%, followed by F2 (schizophrenia, schizotypal, and delusional disorders) at 30%, with no difference in efficacy, indicating that ECT is still performed as 1 of the treatment options for schizophrenia in Japan. The present results suggested that accumulation of annual data from multiple centers can be useful for more effective and safer ECT practices.

Key Words: electroconvulsive therapy, depression, schizophrenia, Japan

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In Japan, electroconvulsive therapy (ECT) was first performed for schizophrenia in 1939,[1] and highly safe, modified ECT using intravenous anesthetics and muscle relaxants was first reported in 1958.[2] However, modified ECT that required the use of anesthetics was not widespread, and the importance of ECT has diminished with the development of antipsychotics and antidepressants since the 1950s.[3] During the 1960s, the use of ECT in Japan decreased by 50%, and it has continued to decrease for more than 30 years.[4–6] In the 1980s, modified ECT performed in collaboration with anesthesiologists became widespread mainly in general hospitals and university hospitals.[7] In recent years, with the increase of elderly patients in Japan, modified ECT has become 1 of the major therapeutic modalities in psychiatric treatment.

Discussions on the safety and ethics of ECT have become vigorous since the end of the 1990s, and the Japanese Society of General Hospital Psychiatry provided guidelines aimed at popularizing modified ECT in 1998 and 2001.[8,9] In 2002, the Ministry of Health, Labour and Welfare and the Pharmaceuticals and

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Medical Devices Agency (PMDA) approved the application of a pulse wave device for the purpose of using modified ECT. Then, the Japanese Society of Psychiatry and Neurology revised the ECT guidelines with the cooperation of the ECT Committee of the Japanese Society of General Hospital Psychiatry in 2006.[10]

Despite the long history of ECT practice in psychiatry in Japan, the current ECT implementation status has still not been clarified. The most common diagnoses of patients who received ECT were depression, schizophrenia, and schizoaffective disorder, but detailed data have not been provided.[11] Although Takebayashi[12] reported the outlook for ECT in Japan in 2010, no large-scale field investigation has been conducted. Moreover, even though a worldwide comparative study reported by Leiknes et al in 2012[13] referred to 2 studies reported by Motohashi et al[11] and Chanpattana et al[14] as Japanese data on ECT, those studies included numerous cases that were given unmodified ECT. When the use of brief-pulse devices was approved by the Japanese Ministry of Health, Labour and Welfare in 2002, it was mandated that the use of such devices be performed only under general anesthesia. Therefore, most of the unmodified ECT treatments using a sine-wave device under intravenous anesthesia have been replaced by the current method. However, the former method has not been officially prohibited, and there are little data on the implementation status of modified ECT in Japan. Especially, it is difficult to state that the worldwide study showed the reality of the current modified ECT treatment scenario in Japan.

The Japanese Society of General Hospital Psychiatry launched the certification system of ECT facilities in 2016. The purpose of the system was to equalize effective and safe treatment with ECT in Japan, and also to provide a guide for patients to find a facility where they can receive ECT, and for senior residents who wish to receive training in ECT to choose training and work sites. Since the certification system is administered by the Japanese Society of General Hospital Psychiatry, only general hospitals are eligible for certification, and single-specialty psychiatric hospitals were not included. However, ECT can be performed in non–ECT certified facilities, and it is also performed in many psychiatric hospitals that are not eligible for certification. The criteria for certification include performing modified ECT with the Thymatron System IV ECT device (Somatics, Inc, Lake Bluff, IL) on at least 10 patients or 100 sessions per year for the past 3 years. In addition, there must be a full-time psychiatrist participating in ECT training hosted by the Japanese Society of General Hospital Psychiatry and a full-time or part-time (at least 32 hours per week) anesthesiologist performing or teaching ECT anesthesia. Moreover, the society required these facilities to submit an annual report on ECT such as patients' age, gender, and diagnoses, and the number of ECT implementations, therapeutic efficacy, adverse events, and so on, as basic data for the equalization of effective and safe ECT, and it began compiling the treatment performance of all ECT certified facilities.

In the present study, based on the annual reports from the ECT certified facilities, we aimed to comprehend the current ECT implementation status in Japan, that is, the number of acute-phase ECTs, diagnoses of patients, therapeutic efficacies, and adverse events.

METHODS

We conducted a multicenter observational study to collect and investigate ECT implementation reports that did not include personal information submitted to the Japanese Society of General Hospital Psychiatry by ECT certified facilities. The study protocol was approved by the Ethics Committee of Nippon Medical School Hospital as representative of ECT certified facilities. The protocol of this study required the approval of the ethics committee of each facility before inclusion of the ECT data. However, approvals had not been obtained from 5 facilities by the time of the data analyses. In addition, 1 facility was withdrawn because the opt-out procedure within the facility was not announced on the Web site. Thus, we evaluated ECT implementation reports collected in 2016 at 21 ECT certified facilities.

ECT was performed with pulse wave devices (Thymatron; Somatics, Inc, Lake Bluff, IL), using brief pulse waves, and stimulating electrodes placed on bilateral frontal regions or bilateral temporal regions. Globally, it is common to start with the right unilateral electrode placement, and then, in the event of inadequate clinical response, a change is made to the bilateral electrode placement or from ultra-brief to brief pulse stimulation.[15] However, in 2016, it was common that ECT in Japan started with the bilateral electrode placement using brief pulse waves. Historically in Japan, ECT has often been indicated for schizophrenia, and bilateral electrode placement has become widely established. Patients with a high risk of side effects, such as the elderly, may be started with right unilateral electrode placement, but in most cases, it is started with bilateral electrode placement. In Japan, the right unilateral electrode placement has become popular as a way to enhance seizures when 100% stimulation by bilateral electrode placement is not effective. Now, even in 2023, there are many facilities that have never performed right unilateral electrode placement. The Japanese Society of General Hospital Psychiatry is considering the recommended augmentation for cases in which it is difficult to induce seizures. Since 2017, the society has recommended changing stimulation to the right unilateral side or changing to ultra-brief pulses as a method of augmentation when effective stimulation cannot be obtained by bilateral stimulation. In Japan, PMDA has approved only Thymatron, but not MECTA. In 2002, when PMDA approved the use of Thymatron in Japan, the maximum output of Thymatron was determined to be up to 100%, consistent with the Food and Drug Administration–approved energy limit in the United States, even though in Europe energy output up to 200% had been approved. Subsequently, in 2018, an application was filed for the approval of Thymatron to use up to 200% energy. After a strict review process, PMDA finally approved the 200% output Thymatron in December 2023. In addition, Japan-manufactured sine-wave ECT devices have been considered obsolete, and the Japanese Society of General Hospital Psychiatry and the Japanese Society of Psychiatry and Neurology strongly recommend the use of Thymatron devices, and modified ECT using Thymatron devices is now widely conducted.

Patients who underwent more than 1 session of acute-phase ECT in 2016 were included. The starting period of acute-phase ECT was between September 24, 2015 and December 26, 2016.

The efficacy of ECT was evaluated according to the Clinical Global Impression-Improvement scale (CGI-I). CGI-I is a 7-point scale ("very much improved," "much improved," "minimally improved," "no change," "minimally worse," "much worse," and "very much worse") that requires the clinician to assess how much the patient's illness has improved or worsened relative to the baseline state at the beginning of the intervention.[16] In this study, the efficacy rates in acute-phase ECT for each gender, age (based on 60 years), and diagnosis were calculated by considering "very much improved" and "much improved" by CGI-I as effective.

Psychiatrists were asked to report any adverse events or side effects that required some treatment or therapy at each ECT session. The options for adverse events and side effects were as follows: cardiac arrhythmia, uncontrollable hypertension, shock, respiratory complication, headache, nausea, myalgia, memory and cognitive impairment, delirium/excitement, manic switch, and

TABLE 1. Number of Patients Receiving Acute-Phase ECT

Diagnosis	*ICD-10*	No. Patients (%)
Depressive episode or recurrent depressive disorder	F3	261 (49.8)
Schizophrenia	F2	109 (20.8)
Bipolar affective disorder	F3	83 (15.8)
Schizotypal and delusional disorders	F2	47 (9.0)
Others		24 (4.6)
Chronic pain		8 (1.5)
Organic mental disorder		6 (1.1)
Parkinson disease		5 (1.0)
Obsessive-compulsive disorder		2 (0.4)
Malignant neuroleptic syndrome		1 (0.2)
Autism		1 (0.2)
Unknown		1 (0.2)
Total		542

others (specifically described). They were also asked to report the number of cases for which ECT had to be discontinued or terminated due to adverse events or side effects. In addition, adverse events belonging to level 3b (requiring intensive treatment or therapy) or higher by Incident/Accident Classification for Patient-Safety[17] (ie, grade 3 or over by Common Terminology Criteria for Adverse Events v5.0[18]) were collected. This classification is unique to Japan, and events of levels 0–3a correspond to grades 1–2, whereas those of levels 3b–5 correspond to grades 3–5.[19]

RESULTS

Distributions of Diagnosis, Gender, and Age, and Efficacy of Acute-Phase ECT

The actual number of patients who received acute-phase ECT at the 21 ECT certified facilities in 2016 was 460, the cumulative total number of patients was 524, and the total number of ECT sessions was 5090.

According to the 2-character category in *International Classification of Diseases*, *10th Revision* (*ICD-10*), 344 of 524 patients (65.6%) were diagnosed as mood disorders (F3), and 156 patients (29.8%) as schizophrenia and schizotypal and delusional disorders (F2). The other 24 patients (4.6%) were described in Table 1 (patients with organic mental disorder including 3 with Lewy body dementia).

Of 485 patients who received acute ECT, excluding 39 patients (7.4%) of unknown age and gender among the 524 patients, 334 (68.9%) were female and 151 (31.1%) were male. The mean age of the 485 patients was 60.4 (SD, 15.9) years, and 57.9% of the patients were 60 years or older.

Regarding the efficacy of acute-phase ECT, Table 2 shows the outcomes (cumulative total number of patients and efficacy rate) at the end of acute-phase ECT for each *ICD-10* category and diagnosis. According to the 2-character category in *ICD-10*, there was no significant difference in efficacy between F2 (schizophrenia, schizotypal, and delusional disorders) and F3 (mood disorders) ($P = 0.139$) by χ^2 test.

Table 3 shows the efficacy for each age and gender, excluding 39 patients of unknown age and gender. There was a significant difference in efficacy between patients under 60 years old and those 60 years or older ($P < 0.001$) among all diagnoses by χ^2 test; the efficacy rate was higher in patients 60 years or older, but there was no significant difference between genders ($P = 0.174$).

Adverse Events of Acute-Phase ECT

Approximately three quarters of the patients had no adverse events of acute-phase ECT. The reported adverse events (including overlapping) of acute-phase ECT were 399 none (72.2%), 55 delirium/excitement (9.9%), 41 memory and cognitive impairment (7.4%), 11 headache (2.0%), 5 manic switch (0.9%), 5 myalgia (0.9%), 3 cardiac arrhythmia (0.5%), 3 uncontrollable hypertension (0.5%), 3 respiratory complications (0.5%), 2 nausea (0.4%), and 15 with other side effects (2.7%).

Acute-phase ECT was discontinued in 27 patients due to adverse events. Among these 27 cases, 4 severe adverse events were reported, 1 case each of Takotsubo cardiomyopathy, tooth agitation/loss, prolonged delirium, and next day's fall/bone fracture. In the cases with Takotsubo cardiomyopathy and prolonged delirium, ECT was discontinued. In the case of tooth agitation/loss, ECT was terminated. In the case of bone fracture, ECT was suspended, and it was resumed after surgery for the fracture.

DISCUSSION

The diagnosis of patients who received acute-phase ECT at the 21 ECT certified facilities was mostly F3 (mood disorders), which was more than twice as many as those with F2 (schizophrenia, schizotypal, and delusional disorders). Previous ECT data from 2005 in Japan showed that patients who received ECT were diagnosed with schizophrenia (48.9%), major depression (37.4%), catatonia (6.8%), mania (4.4%), and dysthymia (0.8%).[14] In other words, F2 (schizotypal and delusional disorders) occupied 55.7% and F3 (mood disorders) 42.6% of the patients. Comparing the diagnoses of patients who received acute-phase ECT in the present study with the data of Chanpattana et al,[14] the rate of schizophrenia decreased remarkably, whereas the rate of mood disorders such as depressive disorder and bipolar affective disorder increased. The proportions of female and elderly also increased.

In addition, compared with ECT indications in Europe and the United States, 1 of the characteristics of the ECT indications in Japan was the high rate of schizophrenia.[13] Although ECT indication for mood disorders has increased and that for schizophrenia has decreased in the present study, even today, 20.8% of ECT is

TABLE 2. Outcomes (Cumulative Total Number of Patients and Efficacy Rate) at the End of Acute-Phase ECT

ICD-10 and Diagnosis		No. Patients	No. Improved Patients	Efficacy Rate (%)	*P*
F2	Schizophrenia, schizotypal, and delusional disorders	156	115	73.7	0.139
F3	Mood disorders	344	274	79.7	
Others		24	11	45.8	
Total		524	400	76.3	

TABLE 3. Efficacy Rate for Each Age and Gender

Age and Gender	Implementation, No. Patients	No. Improved Patients	Efficacy Rate (%)
<20 y	3	1	33.3
20–29 y	18	12	66.7
30–39 y	39	24	61.5
40–49 y	53	37	69.8
50–59 y	91	60	65.9
60–69 y	122	100	82.0
70–79 y	114	91	79.8
80 y ≤	45	38	84.4
Male	151	107	70.9
Female	334	256	76.6
Unknown	39	37	94.9
Total	524	400	76.3

conducted for schizophrenia, and 29.8% for F2 (schizotypal and delusional disorders) as a whole. The indications for ECT are more limited in the United Kingdom, and schizophrenia except for catatonic conditions is not indicated for ECT in the guidelines of the National Institute for Clinical Excellence.[20] On the other hand, indications for ECT by the American Psychiatric Association (APA) are relatively wide, as they are in Japan, although the first line of treatment for schizophrenia is pharmacotherapy in the United States.[21] Compared with Europe and the United States, ECT is more widely practiced in medical institutions in Eastern Europe and Asia, and Indian treatment guidelines indicate various pathological conditions other than catatonia.[22]

The reasons for the position of ECT in the treatment of schizophrenia varying from country to country, and from region to region, have been reported as national differences in medical insurance systems, cultural differences in diagnoses and manifestations, undertreatment of mood disorders in Eastern Europe and Asia,[13] and difficulty in introducing ECT by medical systems in Europe and the United States.[23] With regard to Japan, it may also depend largely on the choices of treatment for schizophrenia. Clozapine was released in Japan, finally becoming available in June 2009. Prior to that, ECT had to be the main treatment for intractable drug-resistant schizophrenia. Even in 2016, which is part of the present study, it seems that the reason why it is used more for schizophrenia in Japan than in Europe and the United States is due to the pharmaceutical gap between Japan and Europe/United States. From July 2009 to December 2015, clozapine was newly started in 1860 patients. At the time point of May 28, 2021, the number of registered patients had increased to 12,215. In the future, when the use of clozapine becomes more common in Japan, the proportion of ECT usage for schizophrenia may decline.

ECT was effective for 73.7% of patients with F2 (schizotypal and delusional disorders), with 38.5% obtaining a "very much improved" level in the study. Only a few previous worldwide, large-scale studies regarding the efficacy of ECT for schizophrenia have existed. The Cochrane Review of 2005 explained that the therapeutic efficacy of ECT alone was inferior to that of antipsychotic drugs alone, and that the combination of ECT and antipsychotic drugs was superior to that of antipsychotic drugs alone.[24] Petrides et al[25] reported that ECT was added to clozapine-resistant patients with schizophrenia, and that 50% of those were "very much improved" and "much improved" on CGI-I.

In Japan, the introduction of clozapine was delayed until 2009, and ECT has continued to play a role in the treatment of drug-resistant schizophrenia. The proportion may decline as the use of clozapine becomes more common in Japan, although, even at present, it is assumed that ECT will be continued in cases for which drug treatment with clozapine remains difficult due to various factors. ECT may play a role not only in the pathology of catatonia, but also in the treatment of refractory cases. Recent reviews have also shown that ECT is not only useful as an augmentation strategy for refractory schizophrenia, but can also be effectively used in patients with schizophrenia under various other conditions such as first-episode schizophrenia, adolescents, catatonia, and so on.[26] Moreover, the efficacy of ECT for patients with clozapine-resistant schizophrenia has also been reported in recent years.[25]

Most of the prior reports on the number of ECT implementations are from mood disorder areas. In the present study, acute-phase ECT was effective in almost 80% of F3 (mood disorders) when efficacy rates were calculated by "very much improved" and "much improved." This was almost the same value as in previous studies.[27–30] In summary, as shown by the various previous studies, the present study revealed that there was no significant difference in the efficacy rate of acute-phase ECT between F2 (schizophrenia, schizotypal, and delusional disorders) and F3 (mood disorders).

Regarding gender differences, a previous study concerning depression reported no gender difference in terms of efficacy.[31] As for age comparisons, as a predictor of treatment responsiveness to depression in previous studies, it has been reported that older patients are more likely to respond.[31] In the present study, the efficacy rate of acute-phase ECT in all diagnoses did not significantly differ in terms of gender, but it was significantly higher in patients 60 years or older than in those under 60 years old.

The adverse events of acute-phase ECT in the present study were mainly delirium/excitement (9.9%), memory and cognitive impairment (7.4%), and headache (2.0%); the frequencies of delirium/excitement and memory and cognitive impairment were slightly high, but the headache frequency was low. The side effects reported in previous studies were delirium from 11% to 36%,[32–34] memory and cognitive impairment from 29% to 79%,[13,35,36] headache from 19% to 60%,[37] manic switch from 6% to 12%,[38] and myalgia at 7%.[37] Compared with those side effect frequencies, the present study showed considerably lower frequencies.

Takotsubo cardiomyopathy, a severe adverse event, is characterized by decreased left ventricular systolic function and is often triggered by mental and physical stress. Cardiac dysfunction is transient and usually resolves spontaneously. It has been reported that Takotsubo cardiomyopathy in cases where ECT was discontinued may have been triggered by the physical stimulation of ECT.[39]

The incidence rate of post-ECT delirium has been reported to range between 3.23% and 18%.[32,40] Available literature has reported that there was no association of age, gender, presence or absence of catatonia, ECT parameters, and the use of various psychotropics with high anticholinergic properties with the development of prolonged post-ECT delirium.[41–43] It can be said that the issue of reliable risk factors for the development of prolonged post-ECT delirium is not yet settled.

The main limitation of the present study is the small number of ECT certified facilities. Therefore, it may not accurately represent the implementation status of ECT in Japan at the time of this survey, namely, in 2016. In addition, it may have been necessary to present the survey items in greater detail. For example, the reasons for termination of acute-phase ECT should also be included in the survey items. Thus, it is clear that we must revise the method of regular surveys in the future. Another limitation is that the ratings of clinical status and reporting of adverse events were not performed by blinded raters, but by clinicians whose objectivity could not be guaranteed.

As of March 2023, the number of ECT certified facilities by the Japanese Society of General Hospital Psychiatry has increased to 54. In Japan, with the enactment of the Clinical Trials Act in 2017, it has become possible to conduct surveys only by reviewing a representative facility, eliminating the need for individual reviews at multiple facilities. We are therefore in the process of streamlining the procedures for ECT certified facilities' participation in the collection of deidentified data. Since our society is a psychiatric medical society in general hospitals, it may be difficult for our society to include only psychiatric hospitals, but we may be able to consider conducting a survey jointly with the Japanese Society of Psychiatry and Neurology. We will consider additional investigational items such as some motor and/or electroencephalogram measures of seizure duration during ECT sessions, the number of treatments per session, changes in electrode placement during treatment sessions, and standardized assessment of cognitive function.

In conclusion, we evaluated the current status of ECT in Japan based on annual reports from 21 ECT certified facilities. Mood disorders (F3) were the most common indication at 65.6%, and schizophrenia, schizotypal, and delusional disorders (F2) were at a lower level of 29.8%. Nevertheless, ECT was still performed as 1 of the treatment options for schizophrenia in Japan. Regarding the efficacy of ECT, we found that ECT is more effective in people aged 60 years or older. On the other hand, there was no significant difference in gender between both schizotypal and delusional disorders (F2) and mood disorders (F3). In regard to safety, the frequency of adverse events was reduced compared with that of previous reports. The results of the present study have suggested basic data for equalizing more effective and secure ECT implementation in Japan.

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