The Use of the Stabilization Period in Electroconvulsive Therapy Research in Schizophrenia : II. Implementation†

WORRAWAT CHANPATTANA, M.D.*, M.L. SOMCHAI CHAKRABHAND, M.D.**,
NITCHAWAN KIRDCHAROEN, M.D.*, YINGRAT TUNTIRUNGSEE, M.D.***,
PISARN TECHAKASEM, M.D.***, YAOWALAK PRASERTSUK, M.S.****

Abstract

Background: Electroconvulsive therapy (ECT) has been used to treat schizophrenia since its inception in 1938. Nonetheless, there has never been a research study documenting the efficacy of ECT in schizophrenia. All ECT studies suffered unexceptable methodological flaws. The authors hypothesized the 3-week stabilization period as: 1) a screening method for ECT responders, 2) a procedure for obtaining a homogeneous group of patients ideally suitable for the continuation treatment study, and, 3) as a part of our relapse criteria.

Method: One hundred and fourteen schizophrenic patients received acute Phase I treatment with bilateral ECT and flupenthixol (12-24 mg/d). After the first sign of clinical improvement, all patients had to pass a 3-week stabilization period during which their clinical improvement had to be sustained. The patients had to receive at least 20 ECT treatments before being considered unresponsive to ECT. Fifty one patients enrolled in the continuation (Phase II) treatment study, and were randomized to the 3 treatment groups.

Results: In Phase I study, 58 patients were ECT responders by our criteria, 43 were non-responders, and 13 were drop-outs. Forty five patients either relapsed or completed the Phase II study, while 6 patients dropped out. By our relapse criteria, 6 of 15 relapsed in the combined C-ECT and flupenthixol group, and 14 of 15 relapsed in both the group treated with C-ECT alone or flupenthixol alone. The use of the stabilization period in this study could complete all three objectives previously described.

Conclusions: The use of the stabilization period is very useful in ECT research in schizophrenia.

Key word : Stabilization Period, ECT, Schizophrenia, Prospective Study, Efficacy

* Department of Psychiatry, Srinakharinwirot University, Vajira Hospital,
** Srithunya Hospital, Nonthaburi 11000,
*** Psychiatry Unit, Vajira Hospital, Bangkok 10300,
**** Psychiatric-inpatient Unit, Faculty of Medicine, Chulalongkorn University, Bangkok 10330, Thailand.

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Although electroconvulsive therapy (ECT) has been used to treat schizophrenia since its inception in 1938[1], its role in treating these patients is still controversial at the present time. There has been a paucity of prospective studies contrasting ECT with pharmacotherapy in schizophrenic patients. This situation also characterizes comparative studies of the combined use of ECT and neuroleptic therapy with neuroleptic therapy alone or ECT alone[2,3].

Research on the use of ECT in schizophrenia has been characterized by a variety of methodological limitations, including uncertain diagnostic criteria, nonrandom assignment to treatment groups, and lack of blind and reliable clinical assessment[2, 4-8]. However, the conclusions that have been suggested by the literature are: 1) ECT is effective in the treatment of schizophrenia, especially among patients with acute exacerbations and/or a relatively short duration of illness; 2) combined ECT and neuroleptic treatment may be more effective than either ECT alone or neuroleptic treatment alone[2-9].

In 1994, the first author conducted 3 pilot studies[4-6] using the hypothesized 3-week stabilization period[5,6], during acute ECT treatment (Phase I study), as: 1) a screening method for ECT responders, 2) a procedure for obtaining a homogeneous group of patients ideally suitable for the continuation treatment study (Phase II study), and, 3) as an important part of our relapse criteria of the Phase II study. These features have been incorporated in the design of this study.

Recently, we conducted a prospective, randomized, single-blind, controlled study of continuation ECT (C-ECT) in schizophrenic patients, comparing over a 6-month period the efficacy of combined C-ECT and neuroleptic treatment with ECT alone and with neuroleptic treatment alone[8].

The primary objective of this study was to test our hypothesized 'stabilization period', using in ECT research in schizophrenia, whether it could complete all three objectives described previously.

METHODS

One hundred and fourteen patients with DSM-IV criteria of schizophrenia[10], who suffered acute psychotic exacerbations, were recruited to our study because of poor or unresponsiveness to prior neuroleptic treatments[7,8]. The inclusion criteria were: 1) age 16-50 years; 2) no serious medical conditions assessed from history, physical examination, and pertinent laboratory tests (CBC, electrolytes, ECG); 3) written consent obtained from the patients and/or their guardians after complete description of the study. The exclusion criterian was known hypersensitivity to drugs used in modified ECT (thiopental and succinylcholine). This study was approved by the Ethics Committee of the Faculty of Medicine of Srinakharinwirot University, and The National Review Board of Research studies in Humans of Thailand. The study was divided into 2 phases.

Phase I (Acute treatment study).

One hundred and fourteen schizophrenic patients received acute treatment as inpatients, except for 15 patients who were treated on an outpatient basis. Flupenthixol was prescribed to each patient just before the first ECT treatment was started. The titration schedule of the dosage of flupenthixol was fixed: 12 mg/day during the first week and increased to 24 mg/day depending on tolerability. The neuroleptics prescribed prior to the study were immediately discontinued and there was no washout period.

ECT was administered three times per week. The ECT devices were a MECTA SR1 and Thymatron DGx. Benzhexol (4-15 mg/day) was used to control extrapyramidal symtoms. Diazepam (up to 20 mg/day) was prescribed to control agitation on a PRN basis. Thiopental (2-4 mg/kg) was used at the lowest dosage to induce anesthesia. Ketamine (1mg/kg) was used as a replacement in patients in whom seizure duration was shorter than 30 seconds at the maximal charge settings of the ECT devices. Succinylcholine (0.5-1mg/kg) served as the muscle relaxant. Bilateral electrode placement was used throughout. In each treatment one adequate seizure was required. An adequate seizure was defined as a tonic-clonic convulsion occurring bilaterally for at least 30 seconds, plus electroencephalogram (EEG) showing evidence of cerebral seizures. The electrical dosing schedule suggested by Duke University for the Mecta SR1 and Thymatron was used[11].

The criterion for clinical response corresponded to a BPRS score of 25 or less, as described elsewhere[4]. The patients who responded, went on to a 3-week stabilization period[5,6]. The stabilization period comprised the following treatment schedule: 3 regular ECT (3 treatments/week) in the first week, then once a week for the second and third weeks (during which BPRS scores of ≤ 25 had to be consistently achieved). If BPRS scores rose above 25 at any time during this period, and the

total number of ECT treatments was less than 20, patients returned to regular ECT treatments and repeated the above schedule again. The patients whose BPRS scores were still more than 25, and had already received 20 ECT treatments, were considered ECT nonresponders. The same considerations applied to the patients who had not shown significant improvement (BPRS > 25) until their twentieth ECT treatment. ECT responders were patients who were able to pass the 3-week stabilization period, during which, the BPRS scores assessed before each treatment were always ≤ 25. Fig. 1 summarizes the conceptual framework of Phase I study, and Fig. 2 presents the diagram of the 3-week stabilization period.

Measures used to assess study outcome were: 1) Brief Psychiatric Rating Scale [BPRS,[12]] assessed just before each treatment, and at the end of the study (1 week after the last treatment); 2) Global Assessment of Functioning [GAF,[10]] assessed before acute treatment, and at the end of the study; 3) and the Mini-Mental-State Exam [MMSE, Thai version,[13]] assessed at the same time as the BPRS. Five psychiatric nurses served as raters, and they were not otherwise involved in any part of the treatment. Each patient was rated by the same nurse. These raters underwent training for 12-24 months. Inter-rater reliability was assessed. Each rater provided ratings simultaneously on 10 patients. Each patient was interviewed by a psychiatrist for 20 minutes. The correlation for BPRS scores across the 5 raters indicated strong reliability (r = 0.93).

Phase II (Continuation treatment study).

Fifty eight patients were able to pass our screening procedure (the 3-week stabilization

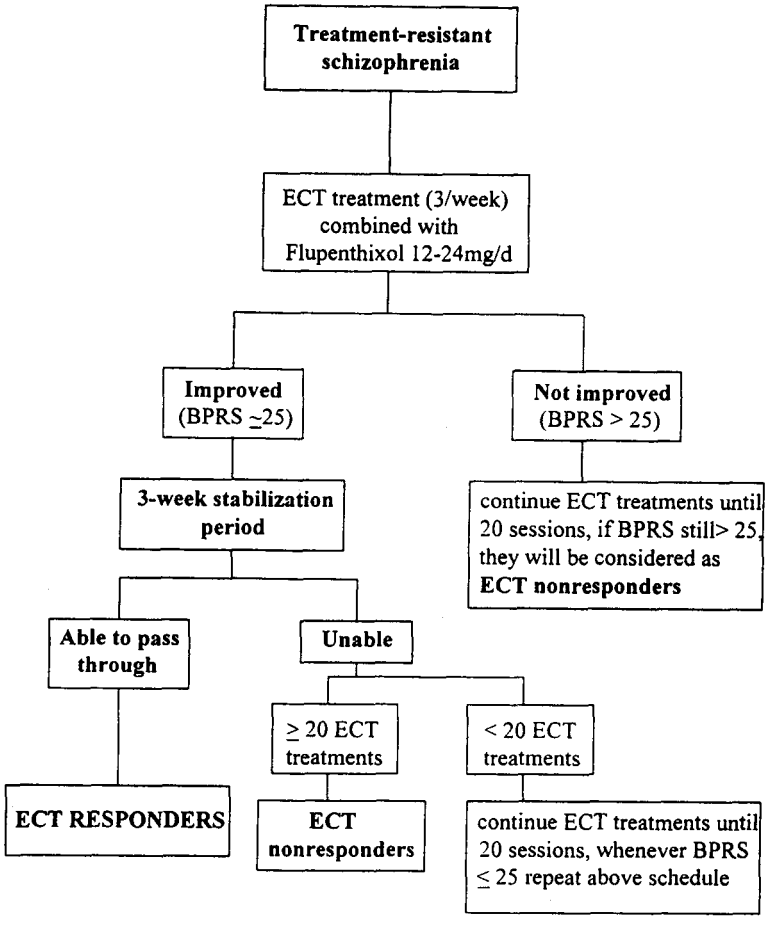

Fig. 1. Conceptual framework of the Phase I study.

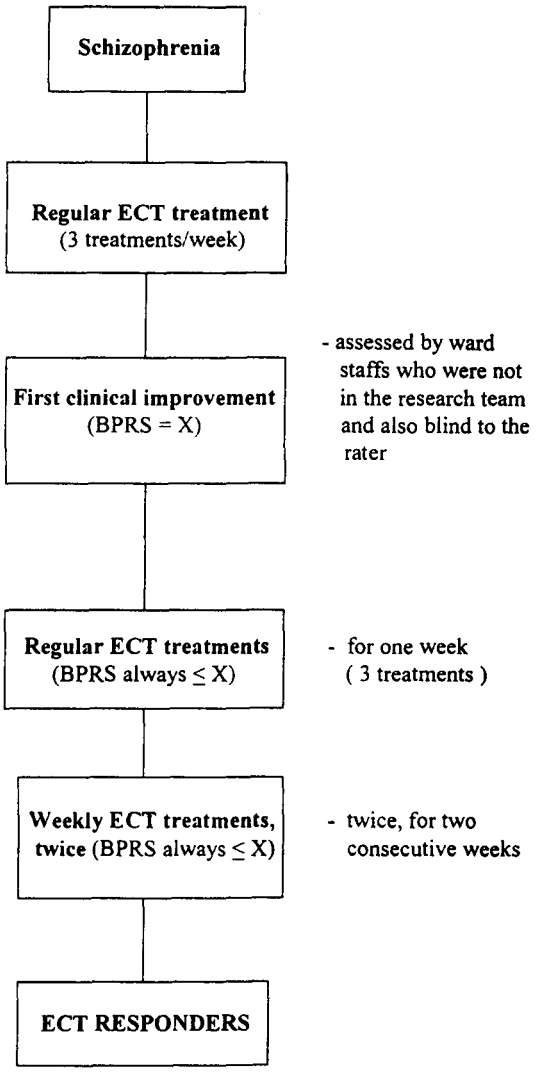

Fig. 2. The 3-week stabilization period.

period) for the continuation treatment study and 51 patients signed a second consent. They were randomized to 3 treatment groups: Treatment I - C-ECT alone, Treatment II - C-ECT combined with flupenthixol, and Treatment III - flupenthixol alone. The key comparison group for this study was Treatment III. The continuation treatment study started 1 week after the last ECT treatment in Phase I, using a fixed treatment schedule for all 3 groups: beginning with weekly treatment for 1 month, then biweekly treatment for 5 months. The duration of the Phase II study was 6 months. The dosage schedule of flupenthixol and benzhexol were the same as Phase I study, and were kept fixed after 8 weeks of beginning Phase II. The ECT treatment procedures were the same as in Phase I. Outcome measurements were: 1) BPRS assessed just before each treatment, and 1 week after the end of Phase II treatment; 2) GAF assessed prior to the first Phase II treatment and 1 week after the end of Phase II treatment; and 3) MMSE assessed at the same time as BPRS. Relapse was defined as BPRS score 25 plus an increase of at least 50 per cent from the maximum baseline BPRS score (that was also 25). Therefore, the minimum BPRS score considered for relapse was 37, that persisted over two consecutive ratings, three days apart[5,8].

Statistical techniques. The results are expressed as mean ± SD. For the discontinuous data, chi-square tests were used to test for significant differences between the groups. When the sample size was small, the Fisher's two-tailed exact test was used. Pair-wise differences between groups on continuous variables were evaluated with *t*-tests.

RESULTS

Phase I.

One hundred and fourteen TRS patients underwent acute treatment. Thirteen patients dropped out, leaving 101 patients in the study. Fifty eight patients were able to pass the stabilization period, and were identified as ECT responders, while 43 patients were ECT nonresponders.

Table 1 shows demographics and clinical characteristics of the 101 patients, as a function of ECT response status. The drop-outs group was excluded from the statistical analysis (Table 2). ECT responders and nonresponders differed in a number of variables. The ECT responders were younger ($t = 3.5$, $p < 0.001$), more frequently presented with the paranoid subtype ($\chi^2 = 4.5$, $p < 0.05$), had shorter duration of illness ($t = 4.0$, $p < 0.001$), shorter duration of the current episode ($t = 6.0$, $p < 0.001$), more psychiatric admissions ($t = 2.0$, $p < 0.05$), higher MMSE scores at entry ($t = 3.5$, $p < 0.001$), and at the end of Phase I ($t = 4.8$, $p < 0.001$), higher GAF at entry ($t = 6.1$, $p < 0.001$), and at the end of Phase I ($t = 11.5$, $p < 0.001$), lower dosage of flupenthixol ($t = 3.9$, $p < 0.001$), received fewer ECT treatments ($t = 8.8$, $p < 0.001$), had a longer motor seizure duration per treatment ($t = 2.4$, $p < 0.02$), and were administered less charge per treatment ($t = 2.1$, $p < 0.05$).

Table 1. Demographics and clinical characteristics of Phase I study (N = 101).

Variable	Responders (N = 58) Mean ± SD (range)	Nonresponders (N = 43) Mean ± SD (range)	P
Age (yr)	33.2 ± 8.0 (20-49)	38.6 ± 7.2 (21-49)	< 0.001
Sex	28 female, 30 male	25 female, 18 male	N.S.
Education (yr)	9.1 ± 3.5 (4-16)	8.6 ± 3.1 (4-14)	N.S.
Subtype*	44P (75.9 %),10D,2C,2U	24P (55.8 %),11D,1C,7U	< 0.05
Onset of illness (yr)	20.8 ± 5.3 (12-35)	20.5 ± 4.2 (15-33)	N.S.
Duration of illness (yr)	12.4 ± 6.7 (3-27)	18.1 ± 7.7 (3-32)	< 0.001
Duration of current episode (yr)	1.9 ± 2.0 (1mo-9yr)	6.5 ± 5.4 (4mo-27yr)	< 0.001
Prior psychiatric admissions	8.1 ± 6.1 (0-26)	5.9 ± 4.3 (1-16)	< 0.05
Prior failure of adequate NT trials	3.3 ± 1.2 (2-7)	3.6 ± 1.3 (2-6)	N.S.
Ave.duration of each NT trial (mo)	22.1 ± 20.5 (1.5mo-17yr)	25.8 ± 25.1 (2mo-12yr)	N.S.
Mean CPZ equivalent dose (mg)	1,231.5 ± 295.2 (825-2,080)	1,239.1 ± 280.2 (833-1,950)	N.S.
Prior failure of flupenthixol	22.41 %	20.93%	N.S.
Prior failure of atypical NT	15.52 %	25.58 %	N.S.
Family history of schizophrenia (in first-degree relatives)	13.79 %	22.86 %	N.S.
BPRS - at entry	49.1 ± 9.6 (37-67)	51.4 ± 9.4 (37-77)	N.S.
- end of phase I study (1week after the last ECT treatment)	18.7 ± 7.2 (3-33)	39.4 ± 8.3 (28-64)	< 0.001
- % of reductions	60.6 ± 17.2 (17.5-91.9 %)	21.7 ± 17.7 (49.3-29.2% increase)	< 0.001
MMSE - at entry	24.1 ± 4.3 (13-30)	20.8 ± 5.2 (12-30)	< 0.001
- end of phase I study	26.4 ± 4.6 (13-30)	21.5 ± 5.1 (14-30)	< 0.001
- % of increments	10.7 ± 17.5 (66.7-27.8% decrease)	7.0 ± 3.0 (78.6-36% decrease)	N.S.
GAF - at entry	30.9 ± 5.7 (22-45)	24.8 ± 3.8 (20-35)	< 0.001
- end of phase I study	49.6 ± 9.7 (30-65)	31.0 ± 4.9 (22-38)	< 0.001
Dosage of flupenthixol (mg)	21.0 ± 4.2 (9-24)	23.6 ± 1.5 (18-24)	< 0.001
Number of ECT treatments	13.9 ± 4.8 (7-25)	20.4 ± 0.8 (20-24)	< 0.001
Seizure duration (per ECT session)			
- motor (sec)	40.2 ± 10.4 (21-67)	36.0 ± 6.6 (26-58)	< 0.02
- EEG (sec)	45.9 ± 12.9 (28-76)	43.9 ± 6.4 (33-55)	N.S.
Average stimulus charge (mC, per ECT session)	243.1 ± 118.6 (54-525.5)	289.8 ± 101.3 (101.9-496.1)	< 0.05
Anesthetics & muscle relaxants (per ECT session)			
- Thiopental (mg)	150.6 ± 28.8 (75-250)	146 ± 19.8 (100-197.1)	N.S.
- Ketamine (mg)	50.6 ± 6.7 (50-75)	52.8 ± 7.0 (50-75)	N.S.
- Succinylcholine (mg)	26.3 ± 9.2 (12.5-75)	24.8 ± 6.7 (12.5-75)	N.S.

*subtype : P - paranoid, D - disorganized, C - catatonia, U - undifferentiated
Other abbreviations: NT - neuroleptic, CPZ - chlorpromazine, N.S. - not statistically significant

There were marked reductions in the BPRS scores of the responder (60.6 ± 17.2%, range: 17.5-91.9%), compared to the nonresponder group (21.7 ± 17.7%, range: 49.3% decrease to 29.2% increase). The BPRS scores at the end of Phase II study of both the responders and nonresponders were in a strikingly wide range (Fig. 3). The average BPRS scores at the first time of clinical improvement was 21.7 ± 3.2 (range: 13-25). Changes in BPRS scores during the stabilization period of the responders are presented in Fig. 4.

Phase II.

Fifty one patients signed a second consent for the continuation treatment study. Of the 51 patients who enrolled in Phase II, 6 dropped out or withdrew consent. Therefore, there were only 45 patients who either completed Phase II study or remained until relapse.

Table 2. Clinical characteristics of the drop-outs of Phase I study (N = 13).

Age (yr)	37 ± 7.2 (24-47)
Sex	5 female, 8 male
Education (yr)	7.9 ± 3.0 (4-15)
Subtype	8 paranoid, 5 undifferentiated
Onset of illness (yr)	19.0 ± 5.0 (12-27)
Duration of illness (yr)	18.5 ± 5.5 (7-24)
Prior psychiatric admissions	9.3 ± 5.6 (2-21)
Prior failure of adequate NT trials	3.2 ± 1.0 (2-6)
Ave.duration of each NT trial (mo)	44.5 ± 33.0 (2.5mo-8yr)
Mean CPZ equivalent dose (mg)	1,241.5 ± 364.4 (933-2,000)
Prior failure of flupenthixol	4 patients
Family history of schizophrenia (in first-degree relatives)	2 patients
BPRS at entry	53.0 ± 10.0 (37-70)
MMSE at entry	22.6 ± 5.4 (14-30)
GAF at entry	28.0 ± 5.9 (20-36)
Dosage of flupenthixol (mg)	21.7 ± 4.6 (12-24)
Number of ECT treatments	8.7 ± 5.2 (1-16)
Seizure duration - motor (sec)	42.2 ± 8.4 (30-59)
- EEG (sec)	49.9 ± 13.6 (34-79)
Ave.stimulus charge used (mC)	219.5 ± 84.9 (101-360)
Anesthetics & muscle relaxants	
- Thiopental (mg)	157.4 ± 24.0 (125-200)
- Ketamine (mg)	50 all (N = 4)
- Succinyl choline (mg)	25.0 ± 5.1 (12.5-37.5)

abbreviation : NT - neuroleptic, CPZ - chlorpromazine

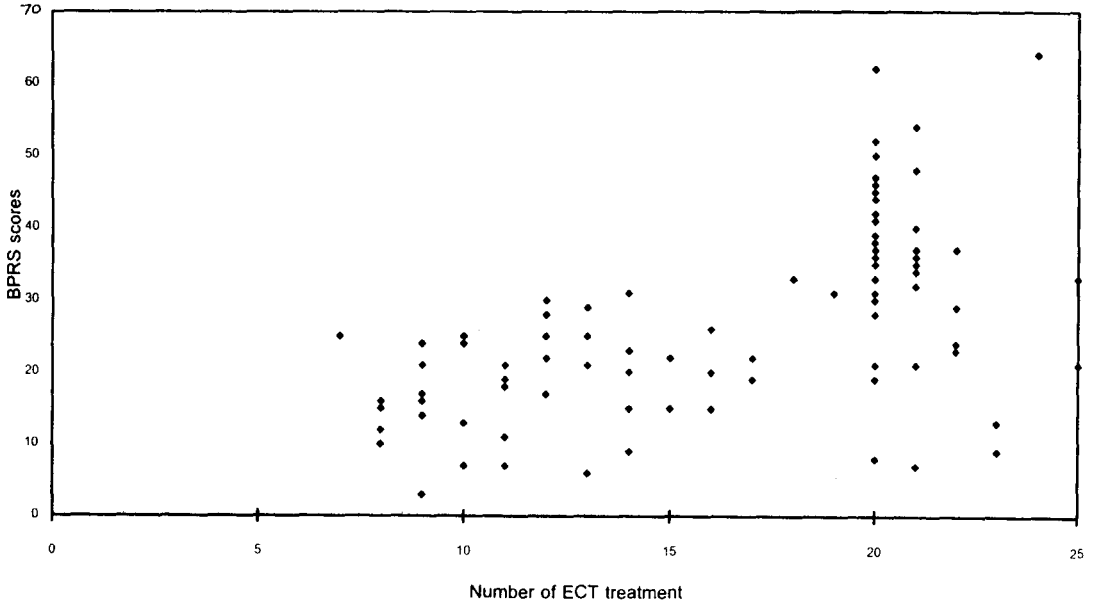

Fig. 3. BPRS scores at the end of Phase I study.

Fig. 5 shows changes in BPRS scores in the completers group, a total of 11 patients; which consisted of: 1 of 15 of Treatment I, 9 of 15 of Treatment II, and 1 of 15 of Treatment III. Changes in BPRS scores in the relapses group (n = 34) are shown in Fig. 6. All of the re-rated BPRS scores, assessed 3 days later, were more than 37.

Phase III study (Maintenance ECT study).

Eight patients in the Treatment II group signed a third consent for a maintenance ECT (M-ECT) study. These patients received M-ECT combined with flupenthixol. The ECT treatment procedures were similar to those in Phase II. No additional treatments were given. There were no recurrences among these 8 patients (Fig. 7).

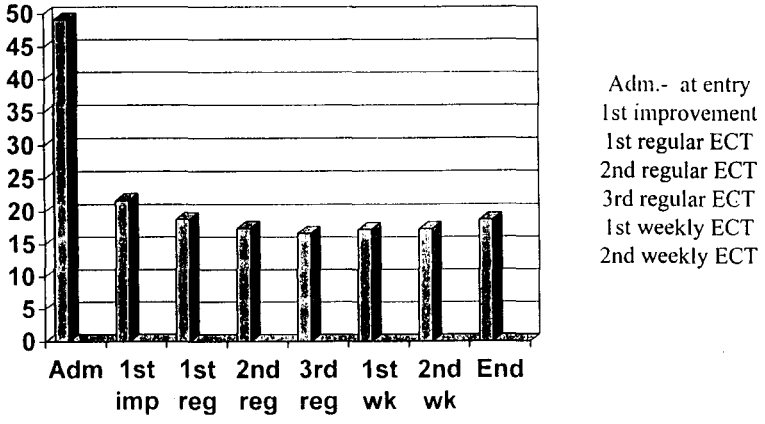

Fig. 4. Changes in BPRS scores of the ECT responders, Phase I study.

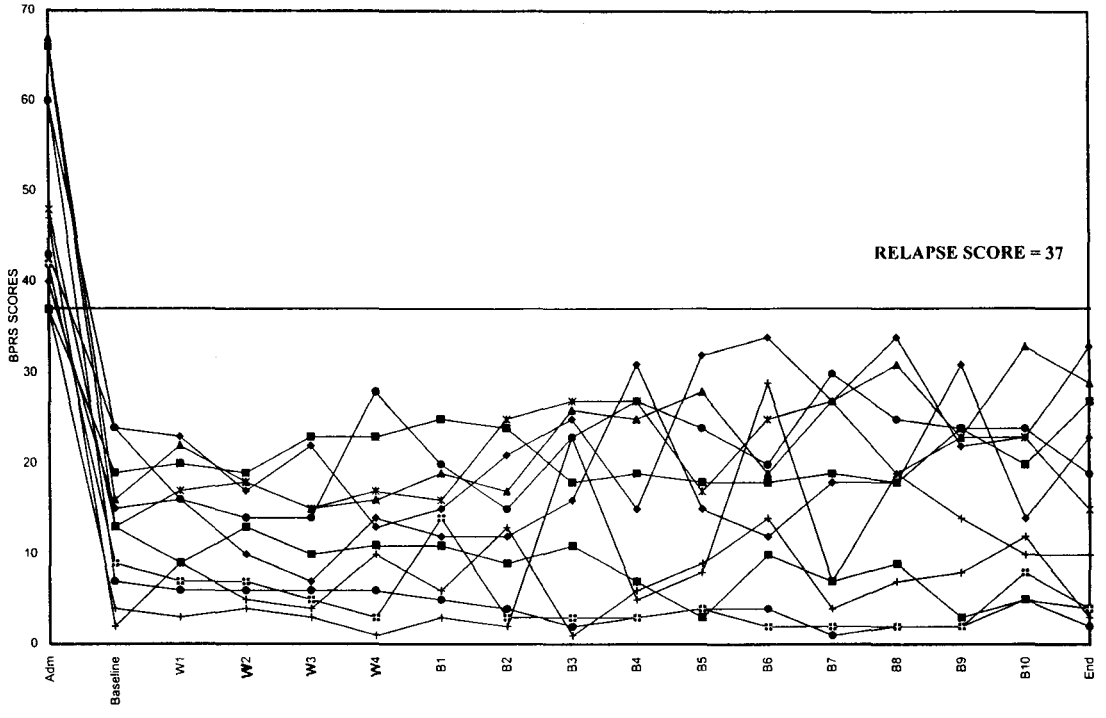

Fig. 5. Changes in BPRS scores of the completers group, Phase II study.

DISCUSSION

Although schizophrenia has long been recognized as a disease, it is best conceptualized as a heterogeneous group of disorders that present with similar psychiatric symptoms. Schizophrenia is characterized by heterogeneous patterns of: etiology, clinical manifestation, treatment response, and courses of illness[14-17]. These varieties have great impact on research studies done in schizophrenia.

In the treatment effectiveness study, there are substantial problems to be considered, for example: 1) Which type of patients should be studied?,

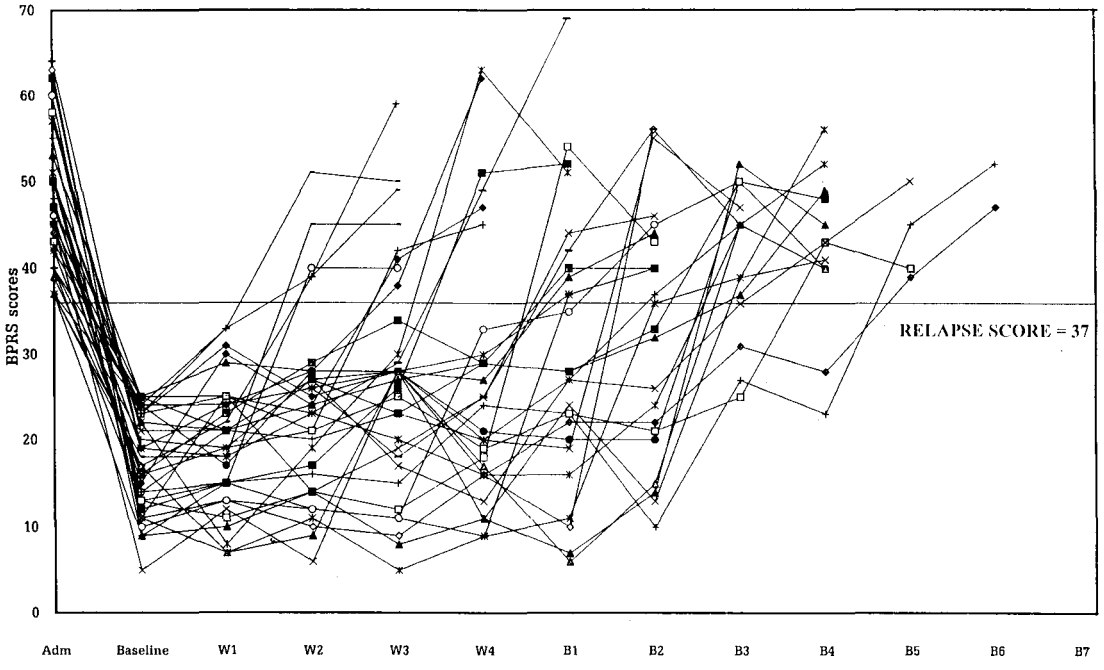

Fig. 6. Changes in BPRS scores of the relapses group, Phase II study.

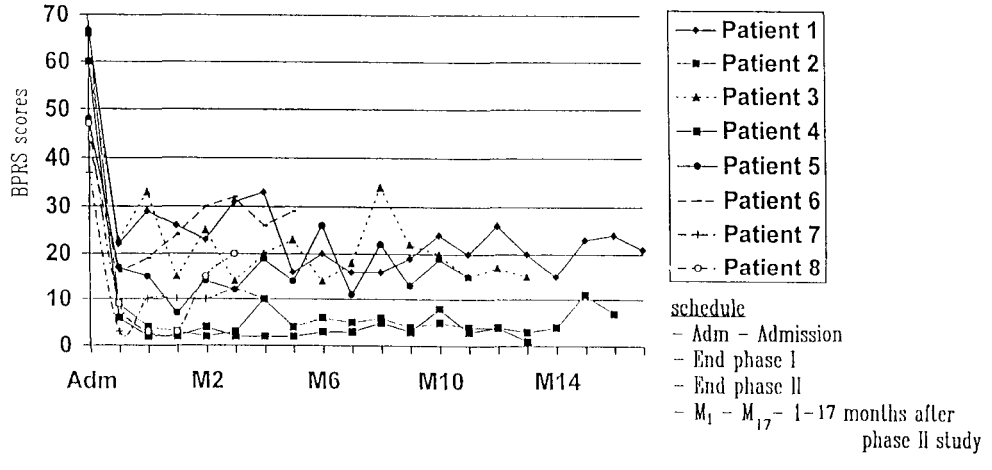

Fig. 7. Changes in BPRS scores of the Treatment II group, Phase III study.

2) Which type of studies should be done?, 3) How to eliminate a number of problems in research methodology?, 4) How to obtain a homogeneous group of patients in the comparison treatment studies?, 5) What are the criterion for treatment response and relapse? In ECT research in schizophrenia, some additional problems should be managed cautiously[6,18]. These are the reasons for conducting the first author's 3 pilot studies[4-6] in order to address some of these problems with the use of the 3-week stabilization period as a method for differentiating the ECT responders from the nonresponders and use of clear-cut criteria for defining relapse.

In summary, 58 of 101 patients were able to pass the 3-week stabilization period, and were ECT responders by our proposed criteria. The responders had marked reduction in their BPRS scores and marked increase in GAF scores, and thus, were apparently distinguishable from the nonresponders. In addition, there were a number of differences in demographics and clinical characteristics between the responders and nonresponders (Table 1). Therefore, the use of the stabilization period might be helpful as a screening method for ECT responders, and thus, could complete our first objective.

There were no statistically significant differences of the responders' BPRS scores in each assessment beginning from the first regular ECT treatment (R1) of the stabilization period to the end of the Phase I study (Fig. 4). Therefore, these patients could represent a homogeneous group of patients that is sorely needed as an ideal sample for the continuation treatment study[18]. Hence, our second objective is also achieved.

We used the BPRS scores at the time of the patients' first clinical improvement as an important part of our relapse criteria. A 50 per cent increase from the maximum baseline BPRS score (which was 25) was required, therefore, the minimum BPRS score to designate relapse was 37, which had to persist in 2 consecutive ratings, 3 days apart[5,8]. The rationale for our relapse criteria was that the relapsed patients should go back to their Phase I entries' clinical conditions (Table 1, our minimum BPRS score at entry to the Phase I study was 37). We did not use the widely adopted measure for treatment responsiveness of a 20 per cent decrease in BPRS scores because this approach suffers from the methodological flaw of a highly differential effect; i.e., an extremely wide range of clinical improvement in patients with either low or high baseline BPRS scores. This approach may result in the majority of patients being partial or suboptimal responders, who continue to have significant symptomatology and functional disability [19-22]. The relapse criteria used here required a substantial and threshold level increase in symptomatology to clearly show clinical worsening.

We also conducted the Phase III study of 8 patients in the Treatment II group. By using the same relapse criteria, there had been no recurrence during the follow-up study of 3 to 17 months after the end of Phase II study (Fig. 7). The results may strengthen the reliability of our relapse criteria. Therefore, the use of the stabilization period might complete our third objective.

Another advantage of using the stabilization period in ECT research is that: the stabilization period and the possibility of reentry into acute treatment should have aided in establishing the optimal number of acute ECT treatments, which is always an important concern when considering when to terminate the acute ECT course[23].

Major limitations of this study are that: 1) there was no comparative data, and 2) we did not test our hypothesis by using any proper statistical analysis. Further study in the use of stabilization period in ECT research is needed.

In summary, the stabilization period is a very useful screening procedure in ECT research in schizophrenia.

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การใช้ช่วงระยะคงที่ในงานวิจัยการรักษาด้วยไฟฟ้าในโรคจิตเภท: เครื่องมือที่สำคัญในงานวิจัย†

วรวัฒน์ จันทร์พัฒนะ, พ.บ., สมชาย จักรพันธ์, พ.บ.**, นิจวรรณ เกิดเจริญ, พ.บ.**, ยิ่งรัตน์ ตันติรังสี, พ.บ.***, พิสาส์น เตชะเกษม, พ.บ.***, เยาวลักษณ์ ประเสริฐสุข, พ.บ.*****

การรักษาด้วยไฟฟ้าถูกนำมาใช้ในโรคจิตเภทตั้งแต่ปี พ.ศ. 2481 แต่จนถึงปัจจุบันก็ยังไม่มีงานวิจัยใดที่สามารถยืนยันประสิทธิภาพในการใช้รักษาผู้ป่วยจิตเภท อุปสรรคที่สำคัญได้แก่ทุกรายงานวิจัยล้วนมีปัญหาของระเบียบวิธีวิจัย คณะผู้วิจัยได้ตั้งสมมุติฐานของการใช้ระยะคงที่เพื่อเป็นเครื่องมือที่สำคัญในการ: 1) คัดเลือกกลุ่มผู้ป่วยที่ตอบสนองต่อการรักษาออกจากกลุ่มที่ไม่ตอบสนอง 2) คัดเลือกกลุ่มผู้ป่วยเพื่อให้ได้กลุ่มที่มีลักษณะคล้ายคลึงกันเข้าสู่งานวิจัยการรักษาต่อเนื่องเพื่อศึกษาเปรียบเทียบประสิทธิภาพการรักษา 3) ใช้เป็นส่วนหนึ่งในเกณฑ์ของการกำเริบของโรค

ผู้ป่วยจิตเภท 114 ราย ได้รับการรักษาระยะแรกด้วยยาร่วมกับการรักษาด้วยไฟฟ้า มีผู้ป่วยสามารถผ่านเกณฑ์ประเมินผลของระยะคงที่รวมทั้งหมด 58 ราย ผู้ป่วย 51 รายสมัครเข้ารับการรักษาระยะที่สองต่อ ผู้ป่วย 45 รายรับการรักษาระยะที่สองจนครบ 6 เดือน (หรือเกิดมีอาการกำเริบขึ้นป

การใช้ระยะคงที่มีประโยชน์มากในงานวิจัยการรักษาด้วยไฟฟ้าในโรคจิตเภท สามารถใช้เป็นเครื่องมือสำคัญในการแยกผู้ป่วยที่ตอบสนองต่อการรักษาได้ชัดเจน ได้กลุ่มผู้ป่วยที่มีลักษณะ homogeneous มากซึ่งมีความเหมาะสมมากต่อการศึกษาการรักษาระยะต่อเนื่องชนิดควบคุม และมีประโยชน์ในการใช้เป็นเกณฑ์ของการกำเริบขึ้นของโรค

คำสำคัญ : ช่วงระยะคงที่, การรักษาด้วยไฟฟ้า, โรคจิตเภท, การศึกษาโดยวางแผนล่วงหน้า, ประสิทธิผล

* ภาควิชาจิตเวชศาสตร์, คณะแพทยศาสตร์ มหาวิทยาลัยศรีนครินทรวิโรฒ, กรุงเทพ ฯ 10300
** โรงพยาบาลศรีธัญญา, นนทบุรี 11000
*** หน่วยจิตเวช, โรงพยาบาลวชิรพยาบาล, กรุงเทพ ฯ 10300
**** แผนกผู้ป่วยใน, หน่วยจิตเวช, โรงพยาบาลจุฬาลงกรณ์, กรุงเทพ ฯ 10330

† นำเสนอในที่ประชุมวิชาการประจำปี Association for Convulsive Therapy, Royal York Hotel โตรอนโต ประเทศแคนาดา วันที่ 31 พฤษภาคม 2541
† ได้รับเงินทุนสนับสนุนจากสำนักกองทุนสนับสนุนการวิจัย