A controlled trial of modified electroconvulsive therapy in Schizophrenia in a Nigerian Teaching Hospital

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Summary

The efficacy of ECT in the treatment of Schizophrenia was investigated in a double blind controlled trial. The ICD - 10 criteria for Schizophrenia were fulfilled by the 20 patients who entered the trial. Consecutive individuals who satisfied the inclusion criteria were randomly allocated to a course of (bilateral) six real or simulated ECTs each as applicable. Sixteen patients completed the ECT treatment and 20 weeks follow up period. Analysis of measures of clinical change (BPRS and SANS Scores) showed that both groups of patients improved, but the improvement of patients receiving ECT was not significantly greater than that of the control group.

Keywords - ***Schizophrenia, Real ECT, Simulate ECT, Outcome.***

Résumé

L'efficacité de ECT dans le traitement de-Schizophrénie a été étudie à travers un rest dirigé à double insu.

Le ICD- 10 critères pour Schizophrénie étaient accomplis par les patients qui se sont inscris pour cette épreuve.

Individus consécutifs qui ont rempli les conditions du critère étaient choisi au hasard pour le cours sur (bilatéral) six vrai ou faux ECT chacun comme applicable. 16 patients ont complété le traitement à travers le ECT et une période de 20 semaines de l'examen de contrôles à long terme. L'analyse de la mesure du changement clinique que les deux groupes de patients manifestaient une amélioration; mais le progrès des patients qui reçoivent ECT n'était pas sensiblement élevé plus que celui du groupe de témoin.

The place of Electroconvulsive Therapy (ECT) in the treatment of schizophrenia is still controversial. Previous studies evaluating ECT and schizophrenia, have been extensively reviewed by various authors such as Kendell[1] and Taylor[2]. who argue that it has no value especially in the management of chronic schizophrenia. Although earlier studies were variously criticised as lacking in clear diagnostic definition and inadequate use of quantitative tools to evaluate results,[3] there had been a few well designed studies in recent time that satisfy contemporary research criteria.

ECT is often combined with neuroleptic drugs in the treatment of schizophrenia, and Taylor and Fleminger,[4] Brandon et al[5] and Abraham and Kulhara[6] have reported well designed studies describing the usefulness of ECT - drugs combination in schizophrenia in the short term. The three studies compared ECT drugs with stimulated ECT drugs. They concluded that the initial improvement witnessed at the beginning of treatment was lost with the passage of time.

In developing countries, schizophrenia is often routinely treated with ECT.[7] Electroconvulsive therapy is still widely used to treat psychiatric patients in Nigeria, [8,9] and even though depression is a common indication for its application, ECT appears to be more widely used for schizophrenia in Nigeria than in the developed nations,[8] without any reported trial of its efficacy in the management of this disorder. It is therefore necessary to find out whether this extensive use of ECT in schizophrenic patients in Nigeria can be justified in terms of improved clinical outcome. The present study was undertaken to fill the gaps created by this dearth of information.

Methodology

The study took place at the Psychiatric unit of the Wesley Guild Hospital, Ilesa, Osun State, the larger of two Psychiatric units of the Obafemi Awolowo University Teaching Hospital Complex, which is responsible for the health care of a population of over one million people. Consecutive patients satisfying the following criteria were included in the study

(a) Fulfilled ICD - 10 criteria for a definite diagnosis of Schizophrenia
(b) Had not received ECT before
(c) Duration of illness not greater than two years
(d) Age at onset of illness not more than 45 years
(e) No history of organic cerebral disease
(f) No significant physical illness.

Patients were allocated to either real ECT or simulated ECT group by ballot without the author's knowledge after they and their relations had given informed consent. Patients received a standard dose of chlorpromazine (300mg daily) for the study period lasting twenty weeks, but the chlorpromazine dosage could be adjusted by the responsible consultant if there was dire need. For some this meant medication for the first time ever or after an interval, for a few continuation of medication and for some a decrease in dose. There was a minimum period of two weeks for patients to be stabilized on their medications before commencement of ECT treatment.

All the patients, except three (one in the simulated ECT group and two in the ECT group) were admitted to hospital. The admission period was for the duration of the ECT treatment.

All patients received a course of (bilateral) six real or six simulated ECTs (twice weekly) each as applicable. Atropine (0.6 - 1.2mg) was given intravenously before the procedure and anaesthesia was induced by thiopentone sodium (200 - 300 mg) followed by suxamethonium (50-100mg). ECT was administered by an ECTRON Duopulse constant current machine delivering 40 pulses per second for 3 seconds via two separate electrodes one in each hand placed in the bitemporal position. To ensure that fitting had occurred, one forearm was always isolated by inflating a blood pressure cuff to above systolic pressure before administering the muscle relaxant. The isolated forearm did not become paralyzed, so the arm component of the siezure could easily be observed. This was recorded for all patients in the Experimental group. The assessor was blind to the treatment groups. The first author blindly assessed all patients before the beginning of the trial using the 19-item WHO modification of the Brief psychiatric Rating Scale (BPRS)[11] the scale for the assessment of Negative Symptoms (SANS)[12], and the Clinical Gobal Impression Scale (CGIS).[13] The assessments were repeated at the end of 2, 4, 6, 8, 12, 16 and 20 weeks.

Categorical variables were analysed with the Fisher's Exact test and the t-test was used to compare means. All the t-tests were one tailed.

Results

There were 20 patients at the start of the trial of which only 16 completed the ECT treatments and twenty weeks follow up period. Of the 4 patients who did not complete trial 2 were in the ECT group, both males, and 2 were in the simulated ECT group, both females.

The analysis and results that follow pertain only to the 16

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patients that completed the trial.

The two groups did not differ significantly on socio-demographic characteristic such as age, sex, marital status and religion or in clinical characteristics such as duration of illness, subtypes of Schizophrenia and number of previous episodes (table 1). They did not also differ in the initial BPRS, SANS and severity of illness (CGIS) scores.

shown in fig. 1 and table 2. There was a reduction in BPRS scores at the 2nd and 4th weeks for both groups but inter-group comparison of BPRS scores at intervals did not show significant differences.

Apart from the total BPRS scores, a composite score of positive symptoms was derived from the scores for conceptual disorganization, grandiosity, suspiciousness, hallucinatory behaviour and

Table 1 Socio-demographic and clinical characteristics of patients

			Absconders		
	Real ECT	**Simulated ECT**	**Real ECT**	**Sim. ECT**	**Remarks**
No of patients	9	7	2	2	
Age (years)			25 & 40	30 & 40	
					t = 0.85 df = 14NS
Mean	27.7	24.3			
SD	10.3	5.5			
Male/Female	4/5	4/3	both males	both females	Fishers Exact Test P = 0.5 NS
Married/ Not Married	8/1	5/2	one married one divorced	both married	Fishers Exact Test P = 0.40 NS
Duration of current illness (months)					
6 months & Under	6	6			
Over 6 months	3	1	2	2	≤6 months VS > 6 months
Mean (SD)	8.4(9.19)	5(6)	14	13	t = 0.8 df (14) NS
No of previous episodes of illness					
One	4	4			Previous VS No
Two	1	0			Previous Episode
None	4	3	2	2	Fishers Exact p = 0.385 NS
Sub types					
Paranoid	5	2	2	2	Paranoid VS
Catatonic	3	1			Non Paranoid
Hebephrenic	1	0			Fishers Exact
Undifferentiated	0	4			P = 023 NS
Means Scores at week 0					
BPRS	22.33(7.83)	19.43(7.28)			
SANS	9.33(6.54)	8.29(5.41)			
BPRSP	10.67(8.65)	7.86(4.74)			
CGIS	5.1(0.78)	4.7(0.76)			
Medication taken during Trial period. (Mean chlopromazine) dosage in mg.	306.5	285			

BPRS - Brief Psychiatric Rating Scale
SANS - Scale for Assessment of Negative Symptoms
BPRSP - Brief Psychiatric Rating Scale (Positive Symptoms)
CGIS - Clinical Global Impression Scale

Table 2 Inter-group comparison of BPRS (Total) Scores

ECT group (n = 9)			SIM. ECT (n = 7)		(df = 14)	
Week	**Mean**	**SD**	**Mean**	**SD**	**t[1]**	**p**
0	22.33	(7.83)	19.43	(7.28)	0.71	NS
2	6.56	(6.23)	8.29	(5.47)	0.55	NS
4	3.67	(4.21)	4.14	(3.85)	0.22	NS
6	7.22	(10.47)	5.19	(7.04)	0.41	NS
8	1.33	(2.50)	3.14	(3.54)	1.07	NS
12	1.11	(1.69)	1.43	(1.81)	0.34	NS
16	1.00	(3.00)	1.57	(4.16)	0.28	NS
20	1.00	(3.00)	1.29	(3.42)	0.16	NS

1 one - tailed test

The response to treatment as indicated by the BPRS scores is

Table 3 Inter-group Comparison of BPRS (Positive) Scores

ECT group (n = 9)			SIM. ECT (n = 7)		(df = 14)	
Week	**Mean**	**SD**	**Mean**	**SD**	**t[1]**	**p**
0	10.67	(8.65)	7.86	(4.74)	0.78	NS
2	4.5	(5.13)	3.34	(3.60)	0.46	NS
4	1.22	(1.86)	2.43	(3.73)	0.72	NS
6	2.78	(5.91)	4.43	(4.16)	0.61	NS
8	0.44	(1.33)	2.00	(3.46)	1.05	NS
12	0.33	(1.00)	1.00	(1.73)	0.85	NS
16	0.44	(1.33)	1.57	(4.16)	0.64	NS
20	0.44	(1.33)	1.29	(3.40)	0.58	NS

1 one - tailed test

unusual thought content.[14]

The means and standard deviations of the BPRS positive scores (BPRSP), for both groups are shown in table 2. Inter-group comparison of BPRSP means scores at intervals from week 0 to week

Table 4 Inter-group comparison of SANS SCORES

ECT group (n = 9)			SIM. ECT (n = 7)			(df = 14)
Week	Mean	SD	Mean	SD	t[1]	p
0	9.33	(6.54)	8.29	(5.41)	0.32	NS
2	2.78	(3.99)	4.57	(5.83)	0.65	NS
4	3.78	(6.30)	1.34	(2.70)	0.95	NS
6	4.11	(5.46)	1.00	(2.24)	1.46	NS
8	1.22	(2.99)	0.29	(0.76)	0.84	NS
12	1.22	(3.67)	0.00	(0.00)	0.94	NS
16	0.67	(2.00)	0.00	(0.00)	0.95	NS
20	0.67	(2.00)	0.00	(0.00)	0.95	NS

1 one - tailed test

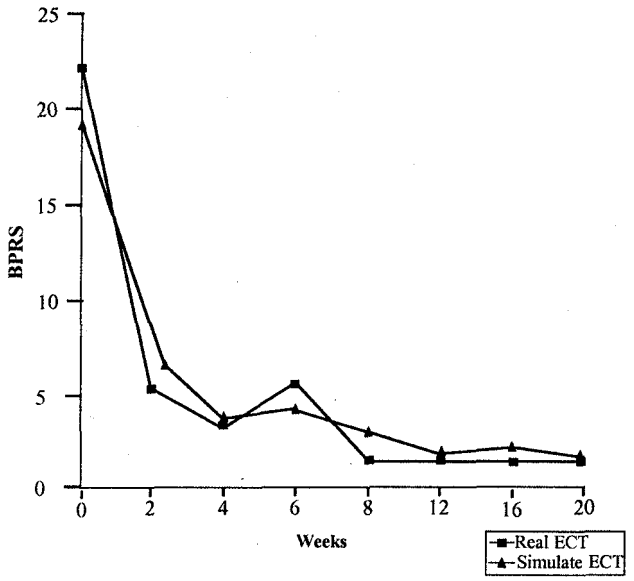

Fig. 1 ***Shows mean Bprs against time (in weeks) for both groups***

20 did not show any significant difference (p>0.05) even though both groups showed a progressive reduction in BPRSP scores from week 0 to week 20.

The means and standard deviations of SANS scores for both groups are shown in table 3. Both groups showed a progressive reduction in SANS scores over time even though inter-group comparison of scores at intervals did not yield any significant difference.

There was no difference between the real ECT group and he simulated ECT group when the CGIS scores were analysed.

Discussion

The study demonstrated that in two groups of patients comparable for age, sex, and duration of illness, the group receiving ECT - neuroleptic did not show any significant advantage over a control group that received neuroleptics alone. There was an improvement in positive as well as negative symptoms in the two groups. The two groups were also comparable in the amounts of drugs consumed during the study period.

The results of this study are quite different from those of Taylor and Fleminger[4], Brandon and co-workers[5] and Abraham and Kulhara.[6]

They had documented the widely held impression that the most important advantage of ECT is in the first 4 weeks; and that this advantage evens out at follow-up. Even though the BPRS scores dropped at the 2nd and 4th week for each group in this study inter-group comparison of scores did not show significant difference.

For this study we decided to limit the number of our ECT application to six to reduce the small although possible risk involved with the treatment and because of the ethical consideration of subjecting the control group to anaesthesia without subsequent ECT. Although no major side effects were recorded for the patients, 4 of them (44%) in the real ECT group complained of headache.

There is no evidence that a fixed number of treatments should be used for ECT, although the typical range is 6 to 12 treatments.[15] Other workers in Nigeria had indicated that six ECTs are adequate for the treatment of most cases of schizophrenia.[8,16]

One important difference of this study from the other trials is that the ICD - 10 criteria was used to make the research diagnoses; whereas the other authors, used the present State Examination CATEGO diagnoses. It is considered highly unlikely that this could explain the different results found in this study.

Miller, Clancy and Cummings[17] maintained that there was no difference between ECT treatment and placebo, so also Greenblatt and co-workers,[18] Smith and contemporaries[19] and Childers.[20] The study by May [21], and his subsequent review in[22], failed to demonstrate the superiority of ECT when compared to drug therapy.

The Royal College of Psychiatrist's Memorandum[23] stated that ECT had no general value when compared to neuroleptic medication.

The present study was limited by the small sample size of twenty patents. Small sample sizes were also observed in previous studies investigating the efficacy of ECT in schizophrenia as reflected in those of Taylor and Fleminger[4] in which 20 patients completed the trial, in that of Brandon and co-workers[5], 17 patients completed the trial out of 19, and in that of Abraham and Kulhara[6], 22 patients completed the trial.

A multi-centre trial in Nigeria in future is likely to overcome this limitation of small example size.

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