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A Double-Blind Controlled Comparison of the Therapeutic Effects of Low and High Energy Electroconvulsive Therapies

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Summary: Patients were randomly allocated to treatment with either low energy pulses, high energy pulses, or high energy sinusoidal wave ECT and, despite the induction of convulsions of similar duration, were found to respond at different rates and to a different degree, depending on whether low or high energy currents were used. It is suggested that the quantity of current, as well as the induction of a convulsion, is relevant to therapeutic outcome with ECT. A re-examination of previous work shows that this is not necessarily inconsistent with these findings, which also explain the contradictory results in recent controlled trials of ECT.

Robin (1981) showed that in 95 courses of treatment, in female patients randomly allocated to low energy pulses or sine wave electroconvulsive therapy, the proportion of pulse treated patients who received seven or more treatments was three times that of sine wave treated patients. In 33 courses of treatment in male patients, similarly randomized, there was no difference in the lengths of courses comparing treatments. It was thought unlikely that the difference between the lengths of courses could be accounted for by failure to produce convulsions. The following study compares patients randomly allocated to 'chopped' sine wave, low energy pulses and high energy pulses for the numbers of treatments prescribed and ratings of depression by doctors blind to the treatment procedures.

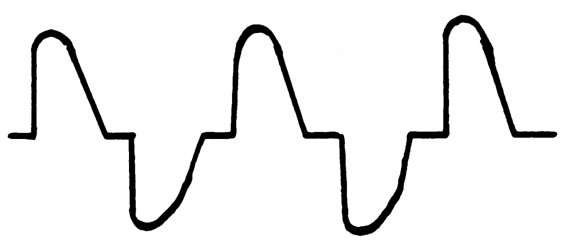
Method

In-patients diagnosed by a consultant as suffering from depression and referred for electro-convulsive therapy were examined by one of two research doctors, using a standard form to obtain actuarial data and previous history. The criteria for admission to the trial were: that depression was the primary condition and not a secondary manifestation of other illness; that the patients were between 20 and 70 years of age; that they were free from physical illness contra-indicating ECT; and that they had not had ECT within the previous six months. Two prognostic scales, (Carney *et al*, 1965; Hobson, 1953) and a depression rating scale (Hamilton, 1960) were administered. Patients in whom the diagnosis of depression was confirmed, who met the other criteria outlined above, and who gave their consent to treatment within the trial, were randomly allocated to one of three ECT regimes —treatment by 'chopped' sine wave currents, by low energy pulses, or by high energy pulses. Patients admitted to the trial were free of medication for at least two days before the commencement of treatment, with the exception of diazepam, 2 mgms, t.i.d., or 5 mgms, t.i.d., in case of severe agitation, and night sedation with nitrazepam, 5 mgms–10 mgms, if required.

Six of seven consultants in the hospital and all the ward nursing staff were 'blind' to treatment procedures; the seventh consultant supervized the treatment centre. Patients were reassessed, using the depression rating scale, after each second treatment in the course, and at the end of treatment; these ratings were undertaken on the first or second day after a treatment. Follow-up assessments at two weeks were planned. The two doctors undertaking ratings did not attend treatment sessions and were consequently 'blind' to the type of ECT used. The duration of the course of treatment was decided by the consultant referring the patient for ECT, and was of variable length.

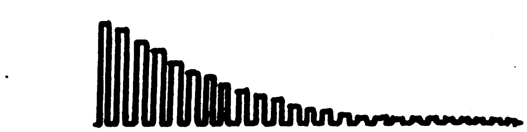
Treatment was conducted in the hospital's treatment centre twice weekly, from 9.00 a.m. Patients were premedicated with atropine, 0.6 mgms intra-muscularly, a half-hour to an hour before treatment. Before the anaesthetic, and twenty minutes after treatment, blood was taken for prolactin estimation. All patients were given intravenous thiopentone, 2 mgms per kilogram body weight, as a bolus, and succinyl choline, 0.4 mgms per kilogram body weight, as near to one minute before treatment as possible. Patients were oxygenated for 10–20 seconds within that time. Bilateral temporo-parietal electrodes were firmly applied to the appropriate degreased scalp area; the negative electrode was always placed on the right side when unidirectional currents were used. Low voltage inter-electrode resistance (range 0.5–5 kilo ohms), the time in seconds during which the current passed, and the energy and charge used in treatment were measured with a meter, constructed by the Southend Hospital Clinical Physics and Bio-Engineering Department, from whom full technical details may be obtained. Sinusoidal wave treatments, 'chopped' to produce a steep initial rise and fall, were provided by the Ectonus Duopulse Mark IV apparatus and supplied 70–100 joules, or 450–900 millicoulombs, (Table II), in 1.7–1.8 seconds. Low energy pulses were provided by the same machine supplying 5.5–13 joules, or 27–52.5 millicoulombs, in 5–5.2 seconds and high energy pulses by the Theratronics 'Transpsycon' machine supplying 40–55 joules, or 185–275 millicoulombs, in 1.2–2 seconds. As will be seen, there is no overlap in the energy or charge supplied in the three treatments. Fuller details of the shape and duration of the pulses and wave forms used (Fig 1) are to be found in Robin (1981) and Pippard and Ellam (1981). An observer with two stop watches timed the period from the release of the anaesthetic bolus into circulation to the administration of the electric current and the time from the latter to the end of the observed fit. Two medical observers (excluding the anaesthetist) were available to confirm that a convulsion had occurred and to correct any decision on the part of the 'timer'. Psychological tests of cognition and resting EEGs were performed at the same points in time as the clinical ratings, and will be the subject of separate reports.

A total of 67 patients were considered for the trial—four were excluded because the research doctors disagreed with the diagnosis of depression. Three further patients were excluded having failed to convulse with a single administration of current at the first treatment (two after low energy and one after high energy pulses). One patient refused to start treatment. One patient is no longer considered after two treatments, as she refused to continue the course; her pre-treatment and first treatment ratings are included in the data. Two others were treated with a different type of current in error after two and four high energy pulse treatments respectively, and only the relevant ratings were included in the analysis. Thus, 59 patients were available for initial rating and after two treatments; 57 patients were available after four treatments, and 56 thereafter. It was not originally intended to change treatments within the trial but, when the treatment team encountered two patients who were still being referred after 14 treatments, and who had both previously responded to fewer than six treatments with an alternative wave form, it was decided to introduce a cross-over after ten treatments. At a later point, when it was apparent that no patient receiving high energy treatments was referred for more than nine treatments, the cross-over was introduced at the tenth treatment session. All those patients who were treated with alternative wave forms after 'failure', as defined above, were initially treated with low energy pulses.



"CHOPPED" SINE WAVE (ECTONUS DUOPULSE MK. IV)

UNIDIRECTIONAL PULSES (ECTONUS DUOPULSE MK. IV)



THERATRONIC "TRANSPSYCON" MONOPHASIC PULSES

FIG 1.

Results

Twenty-four patients treated with 'chopped' sine waves, 17 with low energy pulses and 18 with high energy pulses were available for at least one rating after entry to the trial. The three groups of patients (Table IA) were found to be similar as far as sex was concerned (virtually all female) and to be similar in age, civil status, body weight and occupational status. They were also similar as far as the number of first-degree relatives reported as having had psychiatric treatment was concerned, for the numbers reporting stressful events in the preceding six months, in the duration of the current attack, for previous treatment in the attack, and for previous history of mental illness and of admission to psychiatric hospital. Seventy-five per cent of these patients had undergone previous ECT, and the three groups were matched as far as this was concerned.

The indications for ECT were classified as positive—the type of depression or previous successful treatment, or negative—following the failure of drugs or other conservative treatments. A trend for patients receiving high energy pulses to be included for negative reasons was not statistically significant.

The pre-treatment clinical ratings (Table IB) showed one difference between the groups. The ECT Prognosis Scale (Hobson, 1953) suggested that patients treated with 'chopped' sine waves had a marginally better prognosis than either of the other groups, but particularly than the high energy pulse group. All patients, however, scored less than 7.5—Hobson's (1953) cut-off point for good prognosis. On the other hand, the ECT Index (Carney *et al*, 1965), which is also held to indicate probable prognosis with ECT, showed no significant difference between the groups. The diagnostic index (Carney *et al*, 1965) and the depression scores (Hamilton, 1960) were likewise matched in the three groups.

Within-treatment measures (Table II) showed

TABLE IA (i)

Actuarial historical data of three ECT groups

	Sine wave	Low energy pulses	High energy pulses
Total	24	17	18
Sex			
Female	21	17	17
Male	3	0	1
Age			
< 39	2	3	3
40–59	11	5	5
60	11	9	10
Mean and standard deviation	58 ± 11	56 ± 13	56 ± 15
Civil state			
Single	6	3	2
Married	11	9	11
Previously married:			
Divorced, separated, widowed	7	5	5
Weight in kgs			
Mean and standard deviation	59 ± 13	54 ± 8	57 ± 9
Occupation			
Working	6	6	2
Housewife	10	8	14
Retired	7	3	2
Unemployed	1	0	0
Family history			
First degree relations affected	3	5	7
None affected	21	12	11
Problem areas			
Reported in six months prior to onset	9	6	8
No problems	15	11	10
Duration of current attack			
< 1 month	9	6	5
< 3 months	9	3	2
> 3 months	5	7	10
Unknown	1	1	1

TABLE IA (ii)
Actuarial historical data of three ECT groups

	Sine wave	Low energy pulses	High energy pulses
*Previous treatment—current attack			
Anti-depressant drugs	13	8	8
Major tranquillizers	1	2	1
Minor tranquillizers	4	2	3
Previous mental illness			
Previous illness	20	14	16
No previous illness	4	3	2
Previous ECT			
Previous ECT	17	11	15
No previous ECT	7	6	3
Previous admissions			
Previous admissions	17	14	13
No previous admissions	7	3	5
*Reason for choice of treatment			
Positive indication in type of illness	17	10	4
Positive indication in previous response	11	8	7
Failure of conservative treatment	5	7	8

* Patients may have have had more than one treatment or reason.

TABLE IB
Clinical ratings of three ECT groups

	Sine wave	Low energy pulses	High energy pulses
Prognostic scale (Hobson, 1953)			
Score 1–3	12	4	4
4–5	10	9	6
6–	2	4	8
Mean and standard deviation	3±1	4±1.5	5±2
ECT index (Carney *et al*, 1965)			
Score −8–0	5	4	9
1–7	19	13	9
Mean and standard deviation	3±3	3±3	1±4
Diagnostic index (Carney *et al*, 1965)			
Score 0–5	5	3	7
6–1	19	13	11
?	0	1	0
Mean and standard deviation	7±2	7±2	7±3
Pre-treatment depression score (Hamilton, 1960)			
Mean and standard deviation	24±6	25±6	23±6

prolactin levels before treatment and 20 minutes after treatment to be similar in the three groups, and showed the second reading to be seven to nine times higher than the first (with both sets of measures widely scattered). The rise in prolactin may, according to Trimble (1978), confirm that a convulsion was induced.

Although the anaesthetics were apparently used in different mean doses, reflecting the minor differences in the mean weights of the three groups, it will be

TABLE II

Within treatment measures in three ECT groups

	Sine wave	Low energy pulses	High energy pulses
Prolactin—mu/l			
Before ECT			
Mean and standard deviation	213±194	243±118	230±215
Anaesthetic agents			
Thiopentone, dose in mgms			
Mean and standard deviation	124±20	108±15	113±16
Succinyl choline, dose in mgms			
Mean and standard deviation	25±5	22±3	23±3
Anaesthetic—treatment time in seconds			
Mean and standard deviation	65±14	69±12	66±14
Energy per treatment			
Joules, range	70–100	5.5–13	40–55
Millicoulombs, range	450–900	27–52.5	185–275
Convulsion time in seconds			
Mean and standard deviation	43±16	44±12	43±15
Prolactin—mu/l			
After ECT			
Mean and standard deviation	1664±618	1821±1306	1514±1079
Concurrent night sedation			
Nitrazepam 5 mgms nocte	1	3	5
10 mgms nocte	20	13	12
Concurrent day sedation			
Diazepam 2 mgms t.i.d.	1	0	0
5 mgms t.i.d.	3	0	3

TABLE III

Number of treatments to completion of course or change of treatment

	Sine wave	Low energy pulses	High energy pulses
Number of ECT's administered			
2–3	2	0	3 (+2†‡)
4	5	0	2 (+1†)
5	9	2	1
6	4	5	6
7–8	3	5	2
9+	1	5*	1
Total patients	24	17	15 (+3)
† Treatment changed in error to alternative ECT at this point.			
‡ Treatment refused at this point.			
* Treatment changed in all cases because of failure to respond.			
Number of treatments in course to completion and change because of 'failure' only. Changes by error and refusal excluded §			
Mean and standard deviation	5±2	8±3	5±2

§ Kruskal-Wallis One Way Analysis of Variance (Seigel, 1956). $H = 13.592$, $df = 2$, $P = < .01$.

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appreciated that the margin of error in measurement is probably greater than the differences between the means. Virtually all patients received night sedation and a small number day sedation.

The time from anaesthetic induction to treatment was closely comparable (Table II). The average convulsing time for each of the three groups was very closely comparable, and was based on over 300 individually observed fits.

Patients receiving low energy pulses were maintained on treatment for significantly longer courses (Table III) than those receiving high energy treatments —either sine waves or pulses, and it will be recalled that the number of treatments actually administered in this group was even greater than recorded, as five patients continued ECT after being crossed to another wave form. Only the number of low energy pulse treatments was counted to calculate the means, while the two patients who changed treatment in error and the one who refused to continue treatment in the high energy pulse group were excluded from the calculations of the means. The number of treatments with low energy pulses was thus minimized, while the number with high energy pulses was maximized. No patients changed treatment in the sine wave group.

The depression scale scores (Table IV) were reduced

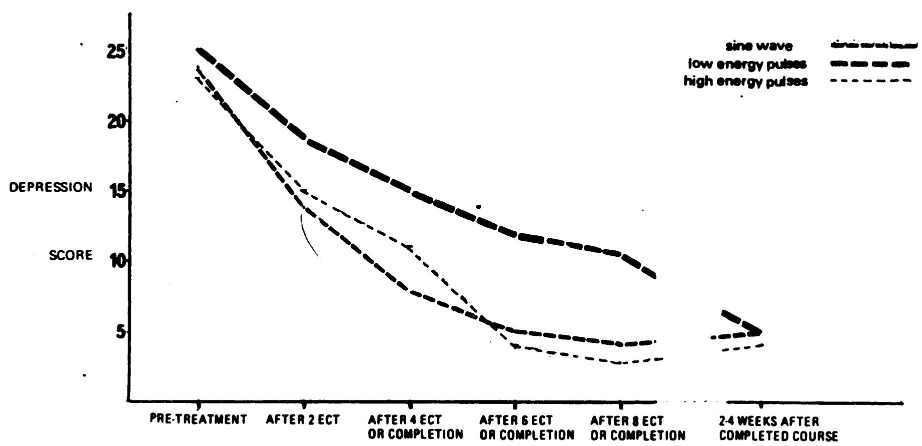

FIG. 2—Hamilton depression scale n three ECT groups.

TABLE IV

Hamilton depression scale scores in three ECT groups

	Sine wave	Low energy pulses	High energy pulses	Kruskal-Wallis One Way Analysis of Variance (Seigel, 1956)
Pre-treatment	24 ± 6	25 ± 6	23 ± 6	
After ECT × 2	14 ± 7	19 ± 7	15 ± 9	H = 13.126, df = 2, P = < .01
After ECT × 4 or completed course*	8 ± 7	15 ± 9	11 ± 10	H = 20.867, df = 2, P = < .001
After ECT × 6 or completed course**	5 ± 6	12 ± 8	4 ± 5	H = 8.018, df = 2, P = < .02
After ECT × 8 or completed course**	4 ± 5	11 ± 8	3 ± 4	H = 5.58, df = 2, P = > .05
2–4 weeks after completed course***	5	5	4	H = 0.85, df = 2, P = > .95

* Two High Energy Pulse (HEP) patients now excluded.
** Three HEP patients now excluded.
*** Four Sine Wave, six Low Energy Pulse, four High Energy Pulse, now excluded.

in all three treatment groups with the progress of treatment, but clearly fell more slowly in the low energy pulse group and not to the same degree within treatment (Fig 2). Using the Kruskal-Wallis One-Way Analysis of Variance (Siegel, 1956), there were significant differences between the scores after two, four and six treatments (or the completed course for those terminated before this number of treatments) but after eight treatments (or completion), the difference was not quite significant at the 0.05 level of probability. The follow-up ratings proved difficult to obtain because of the early discharge of patients—four from the sine wave group, one from each of the low and high energy pulse groups. In addition, eight patients were excluded from consideration because treatment was changed or refused—five from the low energy pulse group and three from the high energy pulse group. The follow-up interviews were conducted in practice two to four weeks after completion, rather than at two weeks, as originally planned. That those who completed a course of treatment were improved to the same degree on follow-up suggests comparable standards were applied by those determining the duration of the courses of treatment, rather than similarity between the overall results.

Discussion

It is widely believed "that the induction of generalized seizure activity in the brain is the crucial element" (Kendell, 1981) in electro-convulsive therapy, and the evidence which is quoted for this belief has three strands. Most double blind trials have shown significantly greater early improvement with ECT compared with 'pseudo-ECT' in which no convulsive or subconvulsive activity was induced (Robin and Harris, 1962; Freeman *et al*, 1978; Johnstone *et al*, 1980; West, 1980). Sub-convulsive treatment yields poorer results than convulsive treatment (Androp, 1941; Ulett *et al*, 1956; Lancaster *et al*, 1958), while alternative methods of inducing seizures, such as leptazol (Palmer, 1942; Pacella and Barrera, 1943) or flurothyl (Small *et al*, 1968; Laurell, 1970) have comparable therapeutic effects to ECT. It will be seen, however, that this evidence describes only an association between convulsions and therapeutic response, and that the necessary support for the determinative or aetiological role of the convulsion, e.g. a direct relationship between the duration of the convulsion and therapeutic response, is lacking.

When Maletzky (1978) measured the duration of each convulsion in the series (mean duration given as 80–90 seconds), summed these times, and then found that total convulsion times of over 210 seconds were required to produce a therapeutic response, he was essentially counting treatments in an unnecessarily elaborate way. Everyday clinical experience supports the view that, where therapeutic response is seen, it is usually after the administration of three or so treatments. Cronholm and Ottosson (1960) found that liminal and supraliminal stimuli produced convulsions of identical duration and type; they compared them with those induced by the liminal stimulus after intravenous lignocaine, which were considerably shorter in duration. These authors reported longer courses of treatment and less therapeutic effect with lignocaine modified treatments than in either of the unmodified groups, and concluded that "where seizures are shortened (by lignocaine) the depression relieving effect of ECT is decreased". Ottosson (1960) points out, however, that the seizures were not simply shortened by lignocaine, but also altered in a number of other, and possibly important ways. "The EEG pattern shows absence of frequent spikes and a rather uniform wave-and-spike pattern with decreasing frequency" while "the muscular seizure pattern is characterized by abolition of the tonic phase". In a later paper (1962), Ottosson says that lignocaine seizure and post-seizure patterns broadly "resemble those described as typical of petit mal epilepsy and myoclonic petit mal"; he also noted "the absence of a significant relationship between the duration of the unmodified grand mal seizure and its therapeutic efficiency". Finally, although there is a similarity in therapeutic response after similar numbers of treatments between chemically induced and electrically induced seizures, Small *et al* (1968) found that the average duration of flurothyl seizures was 104 seconds and that of electrically induced convulsions 45 seconds. Similarly, Laurell (1970) found that flurothyl seizures averaged 120 seconds while electrical seizures averaged 71 seconds. Individual chemically-induced seizures were thus twice as long, but produced similar therapeutic effects.

Robin (1981) has pointed out that while "the emergence of a convulsion is necessary to see a therapeutic effect with ECT it is not certain that the convulsion produces that response. An alternative possibility is that when measures are taken to produce the response a convulsion is unavoidable". According to this proposition, every therapeutic response demands a convulsion, but not every convulsion necessarily implies a therapeutic response. In the present study, different therapeutic effects have been found after similar convulsions induced by different 'doses' of the same stimulus (electrical energy) in three groups of patients, shown to be comparable in numerous ways. The alternative proposition, stated above, is therefore supported.

Our results confirm that convulsions may be induced with small quantities of energy if brief pulses, rather than wide pulses or sinusoidal waves, are used (Friedman and Wilcox, 1942; Liberson, 1948; Weaver *et al*, 1977). At first sight, though, they are not entirely consistent with previous work which compared the therapeutic efficiency of low and high energy treatments (e.g. pulses and alternating currents). Some of this discrepancy may be attributed to methodological flaws in earlier work. Studies by Goldman (1949) and Carney and Sheffield (1974) have shown comparable therapeutic results with different stimuli, but only the latter used ratings for assessment; studies were not blind, did not use random allocation of patients, and the treatments were administered in different eras, "a source of error difficult to evaluate" (Cronholm and Ottosson, 1963). Epstein and Wender (1956) described retrospective data from a hospital, but do not indicate whether the patients were treated within the same or different periods. They found, after limiting the study "to those patients to whom treatment was given and completed in a regular manner" and excluding "any cases where results may have been doubtful or inconclusive", that recovery rates for brief stimulus and sine wave therapies were similar, although the latter may have required fewer treatments. Bayles *et al* (1950) compared treatments within a single year, but the first group of patients were allocated to one method (Brief Stimulus) and, thereafter, alternate patients (not random patients) to either this method or to sine wave treatment. Clinical evaluations showed no difference on therapeutic outcome, but difficulties in evaluating this study arise from discrepancies in the tables, the use of different electrode placements with each treatment, and the inclusion of a group of patients having insulin coma therapy.

Methodologically satisfactory studies, as far as randomization and ratings are concerned, include that of Valentine *et al* (1968), who compared a 'chopped' sinusoidal current with bi-directional brief pulses and separated unilateral and bilateral electrode placements. Patients were randomly allocated, and the Hamilton Depression Rating Scale used before and at the end of treatment, one estimate being undertaken by a clinician 'blind' to treatment. Means of clinical improvement were similar for the different treatments, but Valentine (1978) has said that "the number of patients was too low for an evaluation of treatment" which was not, in fact, the primary purpose of the study.

Cronholm and Ottosson (1960) used a Konvulsator III apparatus (which supplies volleys of pulses) and compared liminal currents (25 per cent–50 per cent over arbitrary 'threshold' adjusted for age) with supra-liminal currents (100 per cent–200 per cent over 'threshold'). These authors found a greater degree of improvement with supraliminal currents after four treatments, but no difference in the number of treatments administered in courses which resulted in similar degrees of improvement by the end of treatment. Improvement thus occurred earlier with supraliminal currents but, from other information concerning Cronholm and Ottosson's techniques (Cronholm and Ottosson, 1963a), it is probable that around 36 joules were compared with at least 48 joules—both high energy loads for pulse treatments. In a further study, the same authors (Cronholm and Ottosson, 1963b) compared the Konvulsator III apparatus with an Elther ES machine delivering brief pulses. Mean energy derived from the first machine is given as 36.5 joules, and for the second 11.4 joules. Some difficulty was encountered in inducing convulsions with the latter which, although attributed to inexperience, may be assumed to demonstrate that the energy employed was close to the convulsive threshold for this type of current. All measures of improvement (ratings and clinical assessments) one week after the course of ECT showed greater change in the higher energy group, but the differences (apart from the global rating) were not quite significant at the .05 level of probability. With higher energy, fewer treatments were required for the course, but the average duration of seizures was the same for the two treatments.

Finally, Weaver *et al* (1977) compared a sinusoidal and a brief pulse stimulus in severely depressed patients, using unilateral electrodes. Patients were randomly allocated to treatment and rated 'blind', using a number of scales. No differences were found between treatments, although the one patient who showed no change was treated with pulses. An average of 47 joules was used in sinusoidal wave treatments and 22 joules with pulses, and significant problems were encountered in this case in inducing convulsions with sinusoidal waves, recognized as arising from the low 'base' employed with this current. In only three of ten patients was a fit induced with every sinusoidal treatment administered and, despite (in 67 per cent of treatments) increasing the original base energy which had been decided for the study, twelve treatments had to be repeated before a convulsion was seen, and in a further six cases, treatment was discontinued without a fit after two attempts. On the other hand, the 22 joules used with pulses is nearly twice the 13 joules it may be calculated Weaver *et al* (1978) used to obtain the "lowest consistent hit" for inducing convulsions with their pulse current and unilateral electrodes. Thus treatment results, while similar, follow under base (near to or below threshold) sinusoidal waves and over base (nearly twice threshold) pulses.

Our findings, if the rate of improvement with low energy pulses is no greater than a placebo effect, throw some light on the discrepancy between Lambourn and Gill's (1978) failure to demonstrate differences between low energy pulse unilateral ECT and placebo, and the positive studies cited above, which used sine wave (Freeman *et al*, 1978; Johnstone *et al*, 1980; Robin and Harris, 1962) or high energy pulse (West, 1980) currents. Our findings suggest finally that the amount of energy, which may still vary depending on the type of current and convulsive threshold for that current, is a factor with influence in the therapeutic outcome of ECT.

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