A Summary Look at CES Studies of Addiction

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Executive Summary

Fifteen studies were analyzed, in which a total of 535 patients were treated for the substance abstinence syndrome with cranial electrotherapy stimulation (CES). The studies were combined statistically in order to get a more confident look at the effectiveness of CES for treating this condition. While most of the studies were of the classic double blind protocol, others used either the single blind or open clinical trial. The result of the analysis showed that the overall effectiveness of CES was 60% improvement. Elsewhere it has been noted (see cognitive dysfunction studies) that the "permanent brain damage" that was said to be a condition of long term substance abuse patients as late as the 1980s, has now been seen to return to within normal functional limits following 3 weeks of daily CES treatment.

Introduction

Meta-analysis is a way of combining the results of many separate studies to see the effectiveness of a treatment when different types of patients are studied, under different study conditions, with different study protocols, and who came to the various studies with differing symptoms accompanying their drug withdrawal.

The goal of clinical studies is always to first test the effectiveness of a potential treatment and secondly to discover which patients the treatment may be most effective in treating. Meta-analysis has the effect of allowing us to essentially study a larger number of patients than can usually be assembled for a single study, and the larger the combined study sample, the greater is the confidence that can be placed in the study outcome: that the study findings are true and accurate. Also, the more diverse the study group is in the combined sample, the more confident can we be in generalizing the study outcome to larger groups of people outside the study. That is, it increases the range of potential types of substance abuse patients that we can predict will be effectively treated with CES.

In the table below is a summary of 15 studies that were combined into the meta-analysis reported on here.

Studies of the Drug Abstinence Syndrome with CES

Study Design	Zr Score[a]	Presenting Group	No. Subjects	Measure Used[b]	Reference
Double Blind	.987	Poly Substance Withdrawal	18	Clinical Rating Scales	1
Double Blind	.397	Cocaine Withdrawal	17	Treatment Responses	2
Double Blind	1.029	Methadone Withdrawal	28	Treatment Records	3
Double Blind	.415	Alcohol Withdrawal	20	Self and Clinical Rating Scales	4

Double Blind	.403	Alcohol Withdrawal	20	Self and Clinical Rating Scales	5
Double Blind	.780	Poly Substance Withdrawal	49	Psychological Tests	6
Double Blind	.671	Poly Substance Withdrawal	60	Self Rating Scales	7
Totals	**4.682**		**212**		
Average	**.669**				
Effect Size[c]	**r = .58**				
Single Blind	.360	Alcohol Withdrawal	85	Psychological Tests	8
Single Blind	.772	Alcohol Withdrawal	47	Self Rating Scales	9
Single Blind	.725	Alcohol Withdrawal	47	Self Rating Scales	10
Single Blind	.737	Alcohol Withdrawal	24	Self Rating Scales	11
Totals	**2.594**		**203**		
Average	**.649**				
Effect Size	**r =.57**				
Open Clinical	.678	Alcohol Withdrawal	53	Physiological Measure	12
Open Clinical	.775	Smoking Cessation	20	Reduced Smoking	13
Open Clinical	.549	Poly Substance Withdrawal	15	EEG	14
Open Clinical	1.065	Marijuana Withdrawal	32	Self Rating Scales, Physiological Measure	15
Totals	**3.067**		**120**		
Average	**.767**				
Effect Size	**r =.65**				

SUMMARY, ALL ADDICTION STUDIES REPORTED ABOVE

Grand Total	**10.343**	**535**	
Average	**.690**		
Total Effect Size	**r =.60**		

a Most studies utilized several (up to 7) improvement measures, and since different percent improvement scores can not legally be averaged, they are converted into Zr scores, averaged, and then converted back to an overall percent improvement (effect size), with the average improvement on all measures reported for each study.

b The Self Rating and Clinical Rating Scales used in the studies all have published reliability and validity measures.

c Effect size, here, is a statistician's basic estimate of the overall percentage improvement by the patients as a result of the treatment.

Discussion

The variety of substances of abuse involved in the above studies were quite varied, and included alcohol, heroin, cocaine, marijuana, and nicotine, among possibly others hidden within the poly substance groups. The measures used in evaluating the response to treatment were also greatly varied. Some involved published clinician's ratings scales, other utilized published patient's self rating scales, while others used psychological tests of various kinds, while yet others combined these along with physiological measures, such as EEG or EMG recordings. While in one study a clinician's rating of treatment response was among the lower measures obtained, in another study the analysis of patient records, both during and following treatment, was among the highest. Also among the strongest responders to the CES treatment were methadone and marijuana patients.

Two of the studies compared the treated and control patients on AMA rates in which the patients left the program against medical advice, and on recidivism rate which measures the number of times a patient returns for additional treatment. In both cases, they found that both the AMA and recidivism rates were reduced by one-half or more in the treated patients.2,7

Researchers earlier received a strong impetus to study CES in substance abuse patients when in the 1970s it was found that the abstinence syndrome, including such features as depression, anxiety and insomnia, was seen to come under control very quickly with CES. Serendipitously it was also discovered that what had up until the 1980s been termed "permanent brain damage" in these patients responded to three weeks of CES treatment by bringing these patients back within their normal functioning range. (See the analysis of cognitive function studies presented elsewhere.)

A word about the study types. In the **open clinical** study, the patients know they are being actively treated for the abstinence syndrome, the clinicians know who is being treated, and the statistician who summarizes the study data also knows, since there is only one group of patient records to analyze.

In the **single blind** study, the patients do not know which are getting treated and which are getting sham treatment, but the clinician providing the treatment knows which are the treated patients. In the single blind study, the clinician doing the post study evaluation of the patients is often blinded to treatment conditions when he completes his evaluation. The statistician is usually blinded also, so that he is given two sets of scores to compare, and doesn't know which group received the treatment. This study design was used earlier on before treatment blinding devices came on stream. In such studies, the treatment was administered sub sensation threshold, in which the clinician turned up the current intensity until the patient just felt it, then turned it back down until the patient said he could no longer feel the stimulation. At that point, the clinician either left the current at that level or turned the unit off (down to, but not including the final click). Because both the patients and the statistician are both blind to the study conditions, some authors have unwittingly published this design as a double

blind experiment. But that term is generally reserved for the true double blind experimental design as described next.

The **double blind** study, the gold standard of science, is usually confined to studies in which neither the patient nor the clinician knows who is being studied. Those designs became available when a double blinding box could be inserted between the patient and the CES device. The double blinding box often had three, four or more settings in addition to a “0” setting in which current flowed freely between the CES unit and the patient. Among the other settings available, some passed current to the patient and some blocked it entirely. The clinician would begin the double blind treatment session by setting all double blinding boxes to the “0” position, would connect the patient to the CES electrodes, turn the current up slowly until the patient signaled he could just feel it, then reduce the stimulus level until the patient signaled that he could no longer feel it. At that point, the clinician set the double blinding box to one of the other settings available and left the patient on the device for 30 minutes to an hour, not knowing who was receiving actual treatment.

Interestingly, in a good double blind experimental design, such as was the case in the majority of those reported in the table above, the persons who were responsible for measuring or rating patient improvement were also blind as to who was treated, as was the statistician who was given anonymous groups of data to analyze. Note that, in effect, that makes such studies quadruple blind, but that term is not used in science.

In the **crossover design**, half the patients get treated the first week or two of the study, while the other half receive sham treatment. In the second half of the study, the formerly treated patients now receive sham treatment while the formerly sham treated patients receive treatment. If the crossover does not involve a sham treatment condition, then the crossover study is treated as an open clinical trial where all patients and staff know who is being treated at each cross of the study. That design is often referred to as a study with “wait in line” controls, in that the patients waiting to begin treatment are tested before and at the end of the waiting period before going into treatment. That is thought to control for environmental factors such as unusual stressors on the 10 O’clock news, any local dramatic weather changes, and so forth.

Interestingly we learned early on in CES work to stay clear of the cross over design in CES studies, after we discovered that the improvement begun by a week or so of CES treatment can often continue after treatment is stopped. That is, the patients continue to get better as time goes on following treatment. One can imagine what that does to the statistical analysis when at the end of the study both groups have improved significantly, but the patients treated first are no longer behaving as good controls should, but are getting even better than the final treatment group is showing. Many otherwise good studies were lost early on due to that effect, and one can see in the table above that the crossover design was wisely avoided in all of the studies reported.

Safety

It is interesting to note that not one problem from negative side effects has ever been reported in any published CES study. Patients undergoing withdrawal for substance abuse are sometimes prone to experience withdrawal seizures. None of the patients undergoing withdrawal in which CES is used has ever been reported to have had a seizure.

One interesting clinical detail we learned early on is that patients who have not been sleeping well when they enter a study – many of them, by definition – sometimes make up for lost REM sleep during CES treatment and have the most vivid, most colorful dreams they have ever had. We learned to warn study participants of this in advance, since some earlier patients associated this with incipient

schizophrenia or some other serious mental condition. Once alerted to the possibility they have always looked forward to the effect with real anticipation.

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