

Noninvasive radioelectric asymmetric brain stimulation in the treatment of stress-related pain and physical problems: psychometric evaluation in a randomized, single-blind placebo-controlled, naturalistic study

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Background: The aim of this study was to investigate the effects of noninvasive radioelectric asymmetric conveyer brain stimulation (REAC-BS) on pain and physical problems, a measurement cluster of the Psychological Stress Measure (PSM) test. When the symptoms of pain and physical problems do not respond to various therapeutic approaches such as medication, physiotherapy, and psychotherapy, they are often called medically unexplained symptoms. As such, these symptoms are reported to be a response to stressful situations or emotional states, often unknown to patients themselves. To explore the effectiveness of noninvasive radioelectric brain stimulation in the amelioration of symptoms of pain and physical problems, we administered a neuropsychophysical optimization protocol using a REAC device.

Methods: The PSM, a self-administered questionnaire, was used to measure psychological stress and pain and physical problems in a group of 888 subjects. Data were collected immediately prior to and following a 4-week REAC treatment cycle.

Results: There was a significant reduction in scores measuring subjective perceptions of stress for subjects treated with one cycle of neuropsychophysical optimization REAC-BS. At the end of the study, the number of treated subjects reporting symptoms of stress-related pain and physical problems on the PSM test was significantly reduced, whereas there was no difference in placebo-treated subjects.

Conclusion: One cycle of neuropsychophysical optimization REAC-BS appears to reduce subjective perceptions of stress as measured by the PSM, particularly on the pain and physical problems cluster.

Keywords: stress disorders, adaptation disorders, medically unexplained symptoms

Introduction

Pain and physical problems of various kinds which display a chronic course and do not meet diagnostic criteria for specific treatments¹ are generally defined as medically unexplained symptoms.²⁻⁴ These symptoms may be present in people of all ages and social groups,⁵ and represent a difficult problem for both general practitioners⁶⁻⁸ and specialists.⁹ Pain and physical problems and medically unexplained symptoms (PPP-MUS) are often considered to be, and treated as, psychiatric disorders.^{6,10-12} However, it may be more accurate to consider PPP-MUS as stress-related maladaptive illnesses¹³⁻¹⁵ or psychosomatic disorders, which are classified as “psychological factors

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affecting medical condition” in the DSM-IV (Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revision).¹⁶ The most common PPP-MUS include migraine, headaches, neck and low back pain, and joint pain. Usually the treatment plan for medically unexplained symptoms involves a combination of behavior modification and pharmaceutical treatment, as well as good communication between patient and doctor. The purpose of the current work is to determine whether the use of noninvasive radioelectric asymmetric conveyor brain stimulation (REAC-BS) is effective in reducing subjective perceptions of stress as measured by the Psychological Stress Measure (PSM) test, a validated questionnaire^{17–19} allowing for the classification of a subject’s stress level and stress-related symptoms of pain and physical problems.

Materials and methods

Participants

Eight hundred and eighty-eight subjects were included in the study from an initial group of 1453 patients (Supplement 1) who attended the Rinaldi-Fontani Institute in Florence, Italy. These patients presented with different types of stress-related PPP-MUS such as migraine, headaches, neck and low back pain, joint pain, and functional somatic pain syndrome. In all subjects, the pain had been present for several years, and patients had found little or no benefit from previous treatments including drugs, physiotherapy, or any of several psychotherapeutic approaches. The subjects included in the study were taking pain medication as needed for unbearable pain, but were asked not to take specific psychotropic drugs. The study was performed in accordance with the Declaration of Helsinki.

Sample size and randomization

This was a naturalistic study, so patients with stress-related pain and physical problems came unsolicited to our private medical center and were observed in normal clinical practice. To obtain a sample of control subjects for comparison with the treated patients, two groups were created. Subjects were randomly assigned to each group using simple computerized randomization by an external operator. Group A subjects received active treatment and Group B subjects received placebo treatment, ie, inactive REAC, in a specific room, in an approximately 3:1 ratio.

Demographic characteristics

Group A included 688 subjects comprising 401 (58.3%) females, of average age 42.3 ± 11.3 years, and 287 (41.7%) males of average age 41.1 ± 11.4 years. These patients were

treated with active REAC. Group B included 200 subjects comprising 123 (61.5%) females of average age 48.8 ± 19.4 years, and 77 (38.5%) males of average age 45.8 ± 18.5 years. These patients were treated with inactive REAC (see Table 1).

Psychological and psychiatric assessment

The PSM was developed specifically to detect stress levels in a nonclinical population.^{17–19} The PSM usually consists of a 49-item self-report pencil and paper questionnaire. In this study, we used an electronic version to collect and process the data, and to analyze the results. Patients were asked to answer questions about their psychological stress using a four-point scale to describe the intensity of their condition (very much = 4, much = 3, little = 2, none = 1). The final score is expressed in total points. To detect the presence of symptoms of pain and physical problems, scores were specifically obtained from questions referring to difficulty with digestion, stomach pain, feelings of a knot in the stomach (question 12), physical aches and pains, including a sore back, headache, stiff neck, stomach ache (question 14), diarrhea or intestinal cramping or constipation (question 28). Both groups of subjects at time 0 were examined by a psychiatrist to detect possible psychiatric disorders that could affect symptoms of pain and physical problems. The average total PSM test score was 122.53 ± 6.75 for Group A and 122.96 ± 7.041 for Group B.

REAC technology and therapeutic protocol

REAC is an innovative medical technology for bioenhancement.^{20,21} REAC-specific treatments have proven efficacious in ameliorating stress-related disorders,^{22–25} depression,²⁶ anxiety,^{25,27} bipolar disorder,²⁸ and other psychiatric disorders.²⁹ REAC administration has also been shown to be effective in treating neuromotor dysfunction,³⁰ post-traumatic pain and injury,^{31,32} and improving functional recovery in arthritic lower limb joints.^{33,34} REAC utilized a typical

Table 1 Demographic characteristics

	Group A	Group B	Total
Gender			
Female	401 (58.28%)	123 (62%)	688 (100%)
Male	287 (41.71%)	77 (39%)	200 (100%)
Age			
n	688	200	888
Mean	41.8	47.7	43.13
SD	11.35	19.14	13.71

Abbreviation: SD, standard deviation.

Table 2 Number needed to treat analysis

	Present	Absent	Total
Given (Group A)	196	496	688
Not given (Group B)	135	65	200
Total	331	557	888
Risk of outcome in treated group		0.2848	
Risk of outcome in control group		0.675	
Absolute risk reduction		0.3901	
Relative risk		0.4220	
Relative risk reduction		0.5779	
Number needed to treat		2.5633	

range of frequencies of 2.4, 5.8, or 10.5 gHz, as selected by the operator for each specific protocol. In the brain stimulation protocols used in this study, a frequency of 10.5 gHz was used with a specific absorption rate of 7 mW/kg. A sequence of seven radiofrequency pulses of 500 milliseconds, termed the neuropsychophysical optimization protocol, was applied by touching the metallic tip of the REAC probe onto seven specific reflex auricular points. This protocol consists of 18 sessions, usually administered on alternate days. The goal of neuropsychophysical optimization is gradual amelioration of symptoms of both physical and mental dysfunction. To achieve this, the amount of treatment given is in relation to symptom severity. The neuropsychophysical optimization treatment is painless, simple, rapid, and noninvasive. The REAC model used in this study was the Convogliatore di Radianza Modulante (ASMED, Italy).

Statistical analysis

Statistical analysis was performed using number needed to treat analysis (Table 2). To compare total points before and after treatment or placebo, the Wilcoxon signed-rank test was used, while the McNemar test was used to test for the presence of symptoms of pain and physical problems. $P < 0.05$ was considered to be statistically significant.

Results

Prior to REAC treatment, 403 (58.58%) patients in Group A were positive for stress-related pain and physical problems.

Table 3 Psychological Stress Measure test results

Subjects	Total points PSM test	PPP subjects (%)	Wilcoxon test
Group A (n = 688), T ₀	122.53 ± 6.747	403	Asymp sig (two-tailed) 0.000
Group A, T ₁	96.01 ± 8.520	196 (48%)	Z = -22.735 P < 0.005
Group B (n = 200), T ₀	122.96 ± 7.041	159	Asymp sig (two-tailed) 0.361
Group B, T ₁	122.11 ± 7.450	135 (85%)	Z = -0.914 P > 0.005

Notes: PSM test results: Total points and Wilcoxon test results obtained in Group A and in Group B, before (T₀) and after (T₁) NPPO REAC treatment/placebo. Values of total points are expressed by mean ± standard deviation. * $P < 0.05$.

Abbreviations: NPPO, neuropsychophysical optimization; REAC, radioelectric asymmetric conveyor; PSM, Psychological Stress Measure; PPP, pain and physical problems; asymp sig, asymptotic significance.

In Group B, pain and physical problems were detected in 159 (79%) patients. Following REAC treatment, only 196 of 403 patients (48.63%) in Group A still presented symptoms of stress-related pain and physical problems (McNemar Chi-square test = 170.426, asymptotic significance = 0.000). In Group B, pain and physical problems were observed in 135 subjects (84.90%). Total point scores decreased significantly in Group A subjects following treatment, from 122.3 to 96.01 (Wilcoxon signed-rank test Z = -22.735, asymptotic significance [two-tailed] = 0.000, Table 3). The decrease in total point scores from 122.96 to 122.11 in Group B was not statistically significant (Wilcoxon signed-rank test Z = -0.914, asymptotic significance [two-tailed] = 0.361, Table 3). There was no significant effect of age or gender upon therapy-induced changes in total points.

Discussion

The REAC reshapes electrical changes due to ion flows,³⁵ which likely balances the distributions of two main neurotransmitters, ie, excitatory glutamate³⁶ and inhibitory gamma aminobutyric acid.³⁷ The neuropsychophysical optimization protocol induces a new positive regulation of bioelectric activity in the central nervous system, leading to normalization of brain function that can be tailored to the individual,^{22-34,38} according to symptoms of pain and physical problems. The current study was designed based upon the results of a previous study that demonstrated the beneficial effects of REAC in stress-related disorders,²⁴ and was targeted to assess specific stress-related clusters on the PSM test.²⁵ The perception of acute and chronic pain may be influenced by stress and the psychological state of sufferers, often without awareness.³⁹⁻⁵⁰ This unrelieved pain may cause the sufferer to use or abuse narcotic drugs, and physicians may prescribe painkillers or tranquilizers to reduce the tension associated with pain.⁵¹ Therefore, a targeted therapy that improves the neuropsychophysical response to environmental stressors could represent a viable alternative to pharmaceutical treatments. REAC is a noninvasive, drug-free alternative

for the treatment of pain, particularly in situations where emotional state and stress levels of the individual clearly affect overall symptomatology.

Conclusion

This research highlights the efficacy of REAC neuropsychophysical optimization on the pain and physical symptoms cluster measurable using the PSM test. The pain and physical symptom cluster represents a set of disorders that can severely impact quality of life in a large proportion of the population. For this reason, it is necessary to find new therapeutic strategies able to treat the various components that underlie these symptoms. Of course, because symptoms of pain and physical problems are often chronic, it is desirable that efficacious treatments also be safe and cost-effective. Further studies are needed to verify the stability of symptoms over time when using more than one cycle of REAC neuropsychophysical optimization, although there may be difficulties in obtaining and following a selected group of patients, especially after treatment. A longer period of observation and administration of additional REAC therapy cycles is necessary to assess the stability of their therapeutic effects over time.

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Disclosure

SR and VF are the inventors of the radioelectric asymmetric conveyer.

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Supplement I

This trial was registered with the Australian New Zealand Clinical Trials Registry (ANZCTR) with the number ACTRN12607000456459. Registration is available at the following link: http://www.anzctr.org.au/trial_view.aspx?ID=82252.

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