

Social anxiety disorder: radio electric asymmetric conveyor brain stimulation versus sertraline

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Purpose: Social anxiety disorder (SAD) is a disabling condition that affects almost 5% of the general population. Many types of drugs have shown their efficacy in the treatment of SAD. There are also some data regarding psychotherapies, but no data are available today about the efficacy of brain stimulation techniques. The aim of the study is to compare the efficacy of noninvasive brain stimulation neuro psycho physical optimization (NPPO) protocol performed by radio electric asymmetric conveyor (REAC) with that of sertraline in adults with SAD.

Patients and methods: Twenty SAD patients on sertraline were compared with 23 SAD patients who refused any drug treatment and who chose to be treated with NPPO-REAC brain stimulation. This was a 6-month, open-label, naturalistic study. Patients on sertraline received flexible doses, whereas NPPO-REAC patients received two 18-session cycles of treatment. Clinical Global Improvement scale items “much improved” or “very much improved” and Liebowitz Social Anxiety Scale total score variation on fear and avoidance components were used to detect the results. The statistical analysis was performed with *t*-test. All measures <0.05 have been considered statistically significant.

Results: Ten of 23 subjects on NPPO-REAC and six of the 20 taking sertraline were much improved or very much improved 1 month after the first NPPO-REAC cycle (t1). Sixteen of the subjects on NPPO-REAC and ten of the subjects taking sertraline were much improved or very much improved 1 month after the second NPPO-REAC cycle (t2). In respect of the Liebowitz Social Anxiety Scale, at t1 NPPO-REAC resulted in statistically more efficacy for sertraline on both fear and avoidance total scores. At t2, NPPO-REAC resulted in statistically more efficacy for sertraline on fear but not on avoidance.

Conclusion: NPPO-REAC is an effective treatment for SAD, allowing substantial and clinically meaningful reductions in symptoms and disability in comparison with sertraline.

Keywords: social anxiety disorder, brain stimulation, REAC, sertraline, fear, avoidance

Introduction

Social anxiety disorder (SAD), also known as social phobia, is characterized by the marked fear of being observed or evaluated by others,¹⁻³ in particular nonrelatives. In such situations, patients with SAD fear that they will say or do something to embarrass or humiliate themselves or that others will notice that they are anxious. Consequently, subjects with SAD often avoid situations^{2,4,5} where such scrutiny might take place, or they endure them with intense distress.⁶ This can result in impaired functioning and disrupted quality of life.^{7,8} Patients affected from SAD may have few social relationships, experience trouble dating, drop out of school^{9,10} or work,¹¹ reject promotions at work, become demoralized, abuse alcohol,¹²⁻¹⁶ and develop other psychiatric disorders¹⁷⁻¹⁹ like major depression.²⁰⁻²² SAD is more frequent in

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the primary care setting,^{23–27} but it is often undiagnosed²⁸ and, consequently, untreated. This low rate of recognition and appropriate treatment reflects the fact that social phobia remains a largely neglected anxiety disorder.^{29,30} However, the available epidemiological studies^{31–33} show a prevalence of at least 5% in the general population.

Most clinicians associate the term “social phobia” with a fear of public speaking. Indeed, social phobia often involves public speaking and, in some cases, does so exclusively. However, there is a variant of SAD that is more pervasive and usually more disabling: generalized SAD^{7,34–37} (gSAD). Subjects with gSAD typically fear and avoid a broad array of situations that most people take for granted, such as speaking in small groups, attending social gatherings, talking to people in authority, and interacting with peers in an informal setting.

The neglect of gSAD obviously extends into the area of treatment. Treatment options for gSAD include monoamine oxidase inhibitors,³⁸ reversible inhibitors of monoamine oxidase A (moclobemide),^{39,40} and, in particular, selective serotonin reuptake inhibitors.^{41–43} Based on their success in the treatment of many mood and other anxiety disorders, selective serotonin reuptake inhibitors have been investigated in the treatment of social phobia, and they are considered as first-choice drugs for the treatment of gSAD. Excluding some psychotherapies,^{44–47} at the moment, no data are available about other therapeutical approaches such as noninvasive brain stimulation techniques like radio electric asymmetric conveyer (REAC) treatments. Neuro psycho physical optimization (NPPO)-REAC has demonstrated efficacy in improving certain psychiatric disorders such as stress-related disorders,^{48–53} anxiety,^{53,54} depression,^{53–55} bipolar disorder,⁵⁶ and behavioral and psychiatric symptoms in Alzheimer disease.⁵⁷ The main goal of the present study was to investigate the efficacy of NPPO-REAC in the treatment of gSAD in patients who refuse drug treatment.

Materials and methods

This was an open-label, naturalistic study. Patients with gSAD came spontaneously to our medical centers and were observed in the normal clinical practice. gSAD was diagnosed with structured clinical interview^{58,59} according to the Diagnostic and Statistical Manual of Mental Disorders, Fourth Edition, Text Revised.

The data for the current study were collected from the Psychic Studies Center, Cagliari, Italy, for 20 patients (Table 1) treated with flexible doses of sertraline^{60–62} (mean dose 125.0 ± 15.5 mg/day once a day) and from the Rinaldi

Fontani Institute, Florence, Italy, for 23 patients (Table 1) who refused drug treatment and were treated with two cycles of 18 NPPO-REAC sessions. The time between the two treatment cycles was about 3 months. None of the patients enrolled in the study had been previously treated for gSAD, and none took psychotropic drugs during the study, except for sertraline. Patients were evaluated for safety and efficacy about 1 month after the end of the first NPPO-REAC treatment cycle (t1) and about 1 month after the end of the second NPPO-REAC treatment cycle (t2). According to the Rinaldi-Fontani protocol, this time period lasted about 6 months and determined the duration of the comparison study. The main efficacy variables were the percentage of responders at t1 and t2, defined as those rated on the Clinical Global Improvement (CGI)^{63,64} scale as 1 (very much improved) or 2 (much improved), and the mean change from baseline at t1 and t2 on the Liebowitz Social Anxiety Scale^{65–67} (LSAS) total score. The LSAS is a 24-item assessment of fear and avoidance of several public-social situations. Statistical analysis of the obtained data was performed using *t*-test, and $P < 0.05$ was considered statistically significant.

Radio electric asymmetric conveyer

The REAC^{68,69} is a medical device that is based on an innovative technology for biostimulation and/or bioenhancement techniques. The model used in this study (Convogliatore di Radianza Modulante, ASMED, Florence, Italy) is specific for noninvasive brain stimulation techniques.

The NPPO-REAC treatment protocol consisted of seven radiofrequency bursts of 500 ms each at a frequency of 10.5 GHz and a specific absorption rate of $7 \mu\text{W}/\text{kg}$, applied by touching the metallic tip of the REAC probe to the ear pavilion.

Results

Both treatments were well tolerated, and no patients suspended the study because of any side effects. At baseline, in both the NPPO-REAC and sertraline groups, for fear and avoidance, a marked clinical picture was detected (Figures 1 and 2).

Ten (43.5%) of 23 subjects on NPPO-REAC and six (30.0%) of the 20 taking sertraline were much improved or

Table 1 Demographics

Treatment	Patients	Male	Female	Mean age (years)
NPPO-REAC	23	8	15	31.4 ± 2.3
Sertraline	20	5	15	30.7 ± 2.8

Abbreviations: NPPO, neuro psycho physical optimization; REAC, radio electric asymmetric conveyer.

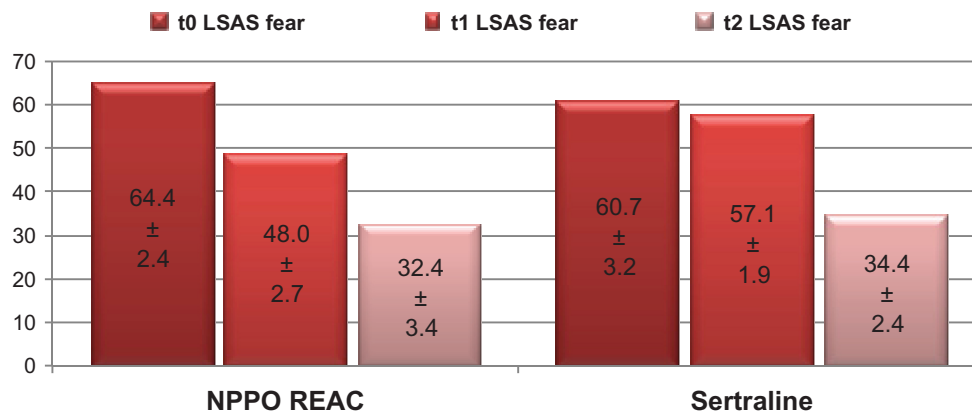


Figure 1 Liebowitz Social Anxiety Scale (LSAS) score decreasing for fear.

very much improved 1 month after the first NPPO-REAC cycle (t1) (Table 2). Sixteen (69.6%) of the subjects on NPPO-REAC and ten (50.0%) of the subjects taking sertraline were much improved or very much improved 1 month after the second NPPO-REAC cycle (t2) (Table 2). The proportion of NPPO-REAC responders (ie, a CGI score of 1 or 2) was significantly greater than for sertraline (Table 2).

At t1, for NPPO-REAC, LSAS total fear score decreased from 64.4 ± 2.4 to 48.0 ± 2.7 (Figure 1) and for sertraline from 60.7 ± 3.2 to 57.1 ± 1.9 (t -test $t = -12.595$, $DF = 41$, $P = 0.000$) (Figure 1); for NPPO-REAC, LSAS total avoidance score decreased from 67.2 ± 4.3 to 50.0 ± 3.2 and for sertraline from 62.4 ± 2.7 to 54.2 ± 2.3 (t -test $t = -4.873$, $DF = 41$, $P = 0.000$) (Figure 2).

From baseline to t1, gSAD improved from marked to moderate both for fear (Figure 1) and for avoidance (Figure 2) in the NPPO-REAC treatment group, and only for avoidance in the sertraline group.

At t2, for NPPO-REAC, LSAS total fear score decreased from 48.0 ± 2.7 to 32.4 ± 3.4 (Figure 1) and for sertraline from

57.1 ± 1.9 to 34.4 ± 2.4 (t -test $t = -2.196$, $DF = 41$, $P < 0.05$) (Figure 1); for NPPO-REAC, LSAS total avoidance score decreased from 50.0 ± 3.2 to 30.5 ± 2.9 (Figure 2) and for sertraline from 54.2 ± 2.3 to 32.0 ± 2.2 (t -test $t = -1.888$, $DF = 41$, $P = NS$) (Figure 2).

From baseline to t2, in both the NPPO-REAC and the sertraline groups, for fear (Figure 1) and avoidance (Figure 2), gSAD improved from marked to subthreshold for both fear and avoidance for NPPO-REAC.

Discussion and conclusion

This is probably the first study that compares the efficacy of a brain stimulation technique with a targeted drug, sertraline, in the treatment of gSAD. The results clearly demonstrate that NPPO-REAC treatment effectively and quickly reduces the core symptoms and the avoidance associated with this disorder. In this research, NPPO-REAC was globally statistically superior to standard dosages of sertraline on selected primary efficacy criteria, CGI improvement, and LSAS total score for fear and avoidance. Considering the early age at onset

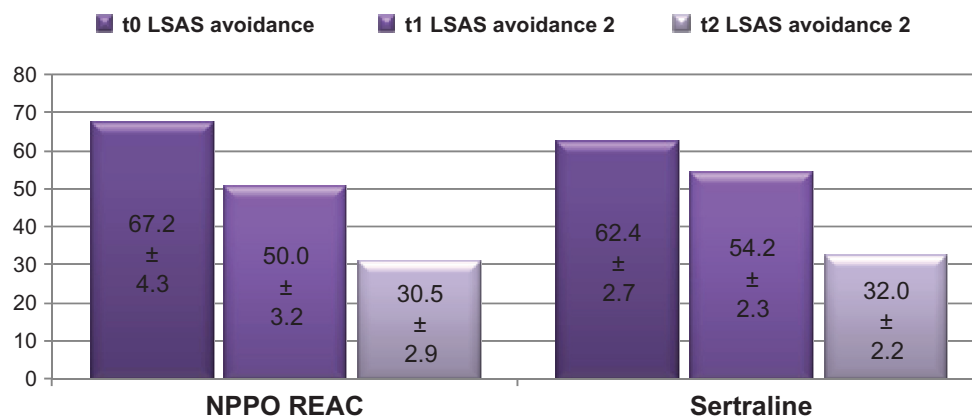


Figure 2 Liebowitz Social Anxiety Scale (LSAS) score decreasing for avoidance.

Table 2 Clinical Global Improvement (CGI)

CGI	Number of patients			
	REAC t1	REAC t2	Sertraline t1	Sertraline t2
Very much improved or much improved	10 (43.5%)	16 (69.6%)	6 (30%)	10 (50%)

Abbreviations: NPPO, neuro psycho physical optimization; REAC, radio electric asymmetric conveyor; t1, first cycle; t2, second cycle.

and chronic course of this disorder, detecting a reduction in disability after only a 6-month follow-up is noteworthy. It is hoped, but remains to be shown in future studies, that longer duration and more cycles of NPPO-REAC treatment might result in even further structuration of results and, consequently, in the reduction of functional impairment.

As previously demonstrated in the treatment of agoraphobia, also in this study a sort of cognitive restructuring performed by NPPO-REAC has been highlighted, in order to guarantee the patient a more rational control of emotions when exposed to social and performance situations and, consequently, better management of the pattern of avoidance behaviors.

In respect of the CGI scale, the greater percentage of patients who felt themselves to be much improved or very much improved with NPPO-REAC than with sertraline highlights the deeper action of the gentle NPPO-REAC brain stimulation compared with the drug.

Another aspect of particular interest is the feeling of natural and no artificial improvement of gSAD symptomatology. This is very important, because typical of anxiety disorders, and probably one of the main reasons of the premature discontinuation of the drug treatment, is the feeling of the artificiality of the results. Therefore, from this point of view, the NPPO-REAC provides greater adherence to the treatment of these patients.

Obviously, there are a number of limitations to this study. SAD is a chronic and disabling disease that in any cases may require long-term therapy. Because of its design, this study did not accurately assess NPPO-REAC efficacy beyond the short, 6-month treatment period. It is possible, although not yet proven, that a longer course of therapy could result in sustained and even greater reductions in impairment and in improvement in quality of life.

Indeed, further studies of long-term treatment with NPPO-REAC are needed to determine the optimal duration of therapy, the number of NPPO-REAC cycles needed, and the efficacy in sustaining remission.

Because NPPO-REAC is also effective in the treatment of depressive symptoms, another limitation of this study is its inability to definitively demonstrate that reductions in social anxiety symptoms were not simply a secondary manifestation of this antidepressant effect.

Conclusion

NPPO-REAC is an effective treatment for SAD, allowing substantial and clinically meaningful reductions in symptoms and disability, in comparison with sertraline.

Disclosure

Salvatore Rinaldi and Vania Fontani are the inventors of the radio electric asymmetric conveyor.

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