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ORIGINAL RESEARCH

Noninvasive radioelectric asymmetric conveyor brain stimulation treatment improves balance in individuals over 65 suffering from neurological diseases: pilot study

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Purpose: In the elderly population, problems with walking and balance are very common. These problems seriously affect the quality of life of the elderly. When gait and balance problems are caused by neurological disease, these problems can be more serious and difficult to handle. The aim of this pilot study was to verify the effect of a noninvasive radioelectric conveyor asymmetric brain stimulation protocol, named neuropostural optimization (NPO), to improve balance in neurological elderly.

Patients and methods: Twelve patients suffering from various neurological diseases participated in this study. They were assessed with the Romberg test, which was performed on a computerized stabilometric platform before, immediately following, and 72 hours after NPO was used to improve balance.

Results: The results showed that a stabilization of balance was recorded in all subjects a few minutes after administration of NPO. This stabilization increased 72 hours after treatment.

Conclusion: The results show that NPO could be a valuable therapeutic approach to improve sensory-motor strategies and neurological control of balance in elderly patients suffering from various neurological diseases.

Keywords: Romberg test, instability, imbalance, gait, REAC, neuropostural optimization

Introduction

In the elderly population, problems with walking and balance[1–5] are very common. These problems adversely affect the quality of life of the elderly and have repercussions that affect not only the autonomy of movement but also other related aspects, such as feelings of insecurity and social and relational skills.[6] It is often difficult to determine the etiology of this disorder.[7,8] When gait and balance problems are caused by neurological disease, the overall situation becomes more serious and difficult to handle both for medical professionals and for the affected person's family. Here, we aimed to offer a treatment option for patients at a rehabilitation center who were suffering from various neurological diseases and gait and balance disorders. These patients showed poor response to rehabilitation treatments. In this study we used a noninvasive radioelectric asymmetric conveyor (REAC) brain stimulation treatment to improve motor strategies in these patients.

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Material and methods

Population

In this open-label study, conducted in accordance with the Declaration of Helsinki, we used neuropostural optimization (NPO) protocol by means of a noninvasive REAC device in a group of twelve patients over the age of 65 years. The patients included eleven women and one man, aged 65–83 years (average age 74.75 ± 5.07 years), who were hospitalized at a rehabilitation center at the same time. The only inclusion criterion was poor response to rehabilitation treatments for the improvement of balance, gait, and stability. Three of the patients treated were suffering from Parkinson's disease, three had chronic cerebral vasculopathy, four had poststroke spastic emisyndrome, one had multi-infarct encephalopathy, and one had ataxia caused by pontine glioma. The Romberg test (RT) was used to assess the patients' difficulty balancing and was performed on a computerized stabilometric platform[9] (CSP) before, immediately after, and 72 hours after the REAC-NPO.

Romberg test

The RT[10–18] is a proprioceptive test that is used to investigate the cause of loss of motor coordination. Specifically, the RT detects the inability to maintain a steady standing posture with the eyes closed. A positive RT suggests that ataxia is sensory, depending on the loss of proprioception. The RT was performed on a CSP able to assess a positive result. The computerized test consists of standing on a platform with the feet together and eyes closed. The CSP assesses a positive RT when the subject sways or even falls. A positive result is sometimes called Romberg's sign.[15,19] The RT was assessed before, immediately after, and 72 hours after the REAC-NPO.

Computerized stabilometric platform

The CSP[20] (Biodex Balance System, Biodex Medical Systems, Inc, Shirley, NY)[21–23] is a system that provides fast, accurate fall risk screening for older adults. CSP assesses the dynamic or static limits of postural stability and clinically tests the sensory integration of balance, returning values in three coordinates: general instability, anterior posterior instability, and latero-lateral instability. Using the CSP, clinicians can assess neuromuscular control by quantifying the ability to maintain dynamic bilateral and unilateral postural stability on a static or unstable surface.

Radioelectric asymmetric conveyor and neuropostural optimization

The REAC (Convogliatore di Radianza Modulante, Asmed, Florence, Italy) uses patented technology[24,25] based on innovative biostimulation and bioenhancement expertise. Specific REAC treatment protocols have proven efficacious in humans for ameliorating stress-related disorders,[26–31] depression,[30,32,33] anxiety,[30,32] bipolar[34] and other psychiatric disorders,[35] motor behavior abnormalities,[36–38] and tissue damage and injuries.[39–41] REAC treatments have also been applied in animals.[42,43] The NPO protocol consists of a single radiofrequency burst for 500 milliseconds applied by touching the metallic tip of the REAC probe to the ear pavilion.

Statistics

The statistical analysis of the data was performed using Statistical Package for Social Science (SPSS), version 13 (Chicago, IL). For this study we used the analysis of variance (ANOVA) test and the Wilcoxon Signed Rank test. The first test, to evaluate the distributions and homogeneity of variance of the instability values, referred to the Romberg test results; the second test was used to evaluate, in the same group, the differences between the data collected over the three periods of observation. The tests and all results with $P < 0.05$ have been considered statistically significant.

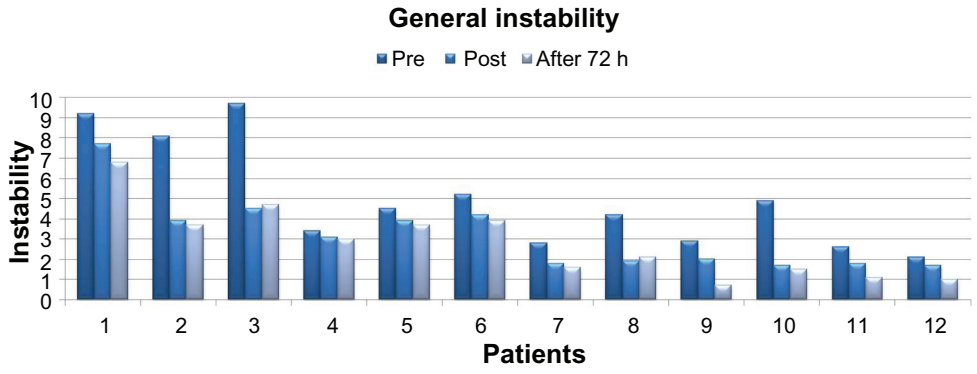

Figure 1 General instability.

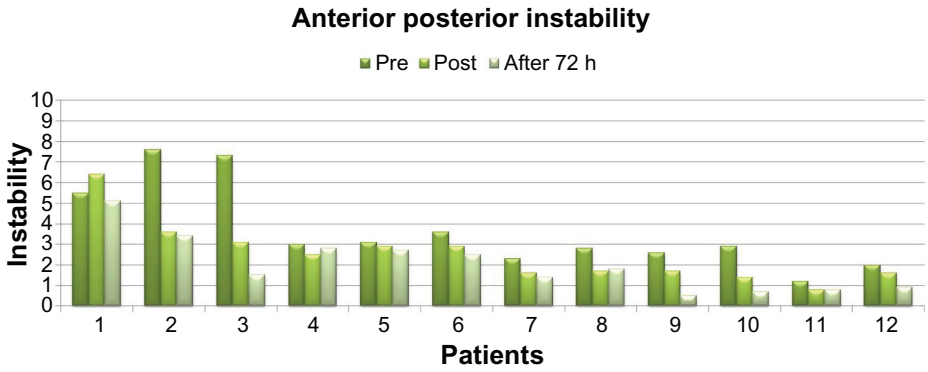

Figure 2 Anterior posterior instability.

Results

The results show that 5 minutes after administration of REAC-NPO, a stabilization of balance was recorded in all subjects (Figures 1–3). This stabilization continued increasing in 83% of subjects 72 hours after treatment (66.67% between t0 and t1 and 16.67% between t1 and t2). The ANOVA test, Wilcoxon test, and Sign test showed that there was a significant statistical trend of the RT values. The best result was observed in the anterior posterior case for the relationship between the t2 and t0 values (Wilcoxon test: $Z = -3.065$ asymptotic significance = 0.002, exact significance = 0.000), which showed an improvement of 45.36%. The worst result was observed in the lateral instability case for the relationship between the t2 and t1 values (Wilcoxon test: $Z = -134$ asymptotic significance = 0.893, exact significance = 1.000), which showed a deterioration of 0.41%. All results were considered statistically significant when $P < 0.005$ (Tables 1 and 2).

Discussion

Aging is a gradual process, although its patterns differ from individual to individual. Over the years, slow changes occur in all tissues, organs, and systems involved in the control and execution of movement. Even in healthy elderly people, there is a progressive reduction in muscle efficiency, which affects both the central and peripheral nervous systems. There is a loss of motor and sensory neurons and receptors, a reduction in the diameters of axons and axonal transport, and increased demyelination,[44] which makes balancing more difficult.[45] In the central nervous system, degenerative phenomena tend to prevail over attempts at compensatory regeneration. Of course, the emotional and psychological states,[46] and alterations in thinking, memory, attention, and problem solving,[47] affect the total loss of motor control and balance. This situation worsens considerably when an elderly person also suffers from a neurological disease. Appropriate therapeutic approaches to treat neurological imbalance in the elderly aim to rehabilitate the activities of the neurological centers of motor control and balance. Therapeutic approaches aim to integrate the peripheral afferents and develop new strategies to better sense motor control mechanisms that are functionally linked to balance.[48] Therapies also use cognitive-postural re-education techniques[46,49] to help patients regain their motor functions and proper body schema. Unfortunately, in clinical practice, this goal is very difficult to achieve, due both to the severity of the disease and to the poor cooperation of elderly patients.

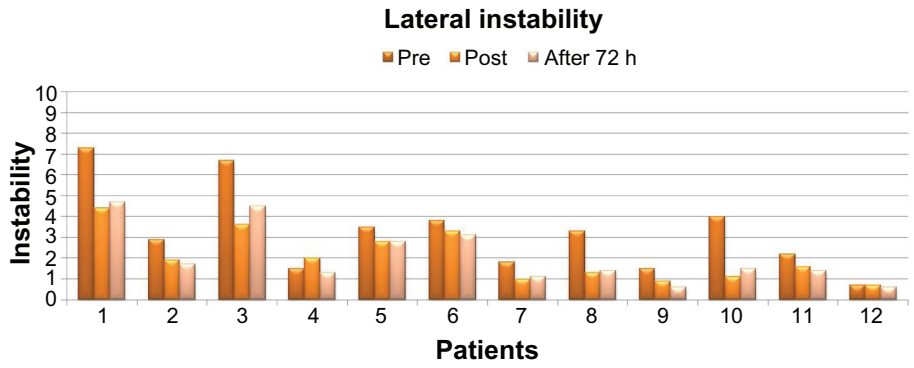

Figure 3 Lateral instability.

Table 1 Performance of balance instability (asymptotic significance [two-tailed])

Variation of instability	Percent		Wilcoxon test	Sign test
GI post-treatment – GI pretreatment[a]	−35.91	Z −3.061	Asymptotic significance 0.002	Exact significance 0.000
API post-treatment – API pretreatment[b]	−31.21	Z −2.474	Asymptotic significance 0.013	Exact significance 0.006
LI post-treatment – LI pretreatment[c]	−37.24	Z −2.805	Asymptotic significance 0.005	Exact significance 0.000
GI 72 – GI pretreatment[d]	−43.60	Z −3.059	Asymptotic significance 0.002	Exact significance 0.012
API 72 – API pretreatment[e]	−45.36	Z −3.065	Asymptotic significance 0.002	Exact significance 0.000
LI 72 – LI pretreatment[f]	−37.00	Z −3.064	Asymptotic significance 0.002	Exact significance 0.000
GI 72 – GI post-treatment[g]	−11.52	Z −2.387	Asymptotic significance 0.017	Exact significance 0.039
API 72 – API post-treatment[h]	−20.20	Z −2.407	Asymptotic significance 0.016	Exact significance 0.065
LI 72 – LI post-treatment[i]	+0.41	Z −134	Asymptotic significance 0.893	Exact significance 1.000

Notes: [a]GI: variation between status after NPO treatment and before NPO treatment; [b]API: variation between status after NPO treatment and before NPO treatment; [c]LI: variation between status after NPO treatment and before NPO treatment; [d]GI: variation between status before NPO treatment and 72 hours after the treatment; [e]API: variation between status before NPO treatment and 72 hours after the treatment; [f]LI: variation between status before NPO treatment and 72 hours after the treatment; [g]GI: variation between status 72 hours after the treatment and after NPO treatment; [h]API: variation between status 72 hours after the treatment and after NPO treatment; [i]LI: variation between status 72 hours after the treatment and after NPO treatment.

Abbreviations: API, anterior posterior instability; GI, general instability; LI, lateral instability; NPO, neuropostural optimization.

Novel therapeutic strategies have been developed, but they have faced these same obstacles. Because REAC technology incorporates a variety of treatment protocols, it may represent a possible solution to address these problems. In previous clinical observations[50–52] the REAC-NPO protocol was shown to induce a long-lasting reversal of some functional impairment, probably by implementing an optimization process of brain activity[51] with a stability of several years. As we observed in this study, the REAC-NPO therapeutic response requires some time (t2) to manifest itself clinically. In fact, after the stimulus (t1), the response is present immediately, but it may be influenced by fear of falling. We also observed that 72 hours after the half-second stimulus, the results showed further improvements compared with the data recorded immediately after the stimulus. Often, this improvement extends to neurological functions and leads to clinical and symptomatic recovery. These data demonstrate that the REAC-NPO protocol, combined with other REAC brain stimulation approaches, could provide elderly patients with neurological disorders with neuropsychological support and the possibility of partial recovery of the biological functions that have been altered by aging.[51,53]

Table 2 One-way analysis of variance (ANOVA) test: instability values referring to Romberg test results

	Test of homogeneity of variances	ANOVA	Robust tests of equality of means
General instability	Levene statistic F 9.593 Significance 0.004	F 16.882 Significance 0.000	Asymptotic F 13.679 Significance 0.002
Anterior posterior instability	Levene statistic F 12.426 Significance 0.001	F 15.050 Significance 0.000	Asymptotic F 12.030 Significance 0.003
Lateral instability	Levene statistic F 3.339 Significance 0.076	F 11.636 Significance 0.002	Asymptotic F 9.861 Significance 0.005

Conclusion

This study can be considered a pilot study. It is the first time it has been performed on a group of neurological subjects who, although not showing cognitive problems, for unknown reasons do not respond to traditional rehabilitative treatment.

These results lead us to conclude that the REAC-NPO could be a valuable therapeutic approach to improve sensory-motor strategies[54] and neurological control of balance. The technique is easy to administer, and it is fast and safe. It can also be applied to other rehabilitation methods. In our clinical experience, we observed that the effects of NPO are stable in the long term (years). Further studies are needed to investigate the potentialities of this technique in balance disorders.

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Disclosure

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

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