Effectiveness of Non-Invasive NESA Neuromodulation in Patients with Multiple Sclerosis: A Case Series Study

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ABSTRACT

Multiple sclerosis (MS) is a chronic, progressive neurological condition characterized by a wide variety of symptoms that significantly impact patients' quality of life. Non-pharmacological treatments such as non-invasive neuromodulation have gained relevance in recent years. This study aimed to evaluate the effects of non-invasive NESA neuromodulation on sleep quality, fatigue, heart rate variability (HRV), and neurogenic urinary incontinence in patients with MS. A retrospective case series was conducted with eight patients diagnosed with different types of MS. All participants underwent 15 sessions of NESA neuromodulation (3 times/week over 5 weeks). The Pittsburgh Sleep Quality Index (PSQI), Modified Fatigue Impact Scale (MFIS), International Consultation on Incontinence Questionnaire-Urinary Incontinence Short Form (ICIQ-UI SF), and HRV measures (SDNN and RMSSD) were assessed before and after the intervention. Statistical analysis revealed a significant improvement in sleep quality ($p = 0.020$), while other variables such as urinary incontinence, fatigue, and HRV showed clinical improvements that were not statistically significant. Most participants reported subjective benefits, including fewer nocturnal awakenings, improved perceived rest, enhanced concentration, and better urinary control during the day. Non-invasive NESA neuromodulation significantly improved sleep quality and demonstrated clinically relevant improvements in fatigue, autonomic function, and urinary symptoms in patients with MS. Given the small sample size, further research is warranted to confirm these preliminary findings and explore neuromodulation as a complementary therapy in MS rehabilitation programs.

Keywords: Multiple sclerosis, sleep quality, fatigue, urinary incontinence, electrotherapy

INTRODUCTION

Multiple sclerosis (MS) affects approximately 2.8 million people worldwide [1] and is characterized by demyelinating, inflammatory, and progressive lesions of the central nervous system [2, 3]. In the early stages of the disease, relative preservation of axons is observed, whereas in later stages these axons become compromised [4]. The etiology of MS remains unknown; however, the most widely accepted hypothesis suggests an autoimmune origin, although environmental and genetic factors are also being investigated [3].

The symptoms of MS vary depending on the degree and location of axonal demyelination. These may include motor impairments, ataxia, spasticity, sensory disturbances, fatigue, urinary dysfunction, and neuropathic pain, among others [5]. This symptomatology significantly impacts sleep quality and overall quality of life in affected individuals [6].

Given the degenerative nature of MS, therapeutic approaches focus on alleviating or stabilizing symptoms, tailored to the patient's specific condition, progression, severity, and clinical presentation. Treatment strategies may differ depending on whether the disease manifests with relapses or in a progressive form. Consequently, a wide range of both pharmacological (e.g., immunosuppressants, corticosteroids) and non-pharmacological

interventions (e.g., physiotherapy, stem cell therapy, neuromodulation) are available [7].

Sleep disorders are 3 to 5 times more prevalent in individuals with MS compared to the general population, making them a significant clinical concern and highlighting the need for alternative treatment options [8].

Non-pharmacological treatments such as neuromodulation are gaining relevance in the management of patients with MS. Their use has been associated with potential reductions in symptom severity and improvements in quality of life. Promising results have been reported in studies using neuromodulation for managing overactive bladder [9], fatigue [10], and neuropathic pain [11], among other symptoms. NESA neuromodulation (an acronym in Spanish for *Neuromodulación Eléctrica Superficial Aplicada* or Applied Superficial Electrical Neuromodulation) is a non-invasive technology that delivers painless and imperceptible low frequency microcurrent signals (less than 1 mA). These signals help regulate autonomic nervous system functions, including sleep, urinary incontinence [12], vascular regulation [13], and even occupational performance [14].

Therefore, the objective of this study is to assess whether the application of non-invasive NESA neuromodulation treatment can improve sleep quality, fatigue, heart rate variability, and the control of neurogenic urinary incontinence in patients with multiple sclerosis.

MATERIALS AND METHODS

Design of the Study

This is a retrospective case study involving nine participants diagnosed with multiple sclerosis who were treated with a non-invasive neuromodulation device (NESA XSIGNAL®).

Sample

A non-probabilistic convenience sampling method was used. Recruitment took place at the Multiple Sclerosis Association of the region where the study was conducted. This facilitated the selection of patients with the condition who agreed to participate in the study. The inclusion criteria were as follows:

- Adults over 18 years old diagnosed with multiple sclerosis and affiliated with the regional Multiple Sclerosis Association.
- Diagnosis of multiple sclerosis for at least 12 months.
- Adequate cognitive capacity to participate in the study.

Exclusion criteria included individuals with contraindications for receiving neuromodulation therapy: internal bleeding, cardiac pacemakers, ulcers, acute thrombophlebitis, electro-phobia, psychotic disorders, active infectious or neoplastic processes, or failure to sign the informed consent form.

Procedure

The intervention protocol used in this study involved the application of the NESA XSIGNAL® device in 60-minute sessions, conducted once per day, three times per week, over a five-week period (15 sessions). Throughout these 15 sessions, the treatment protocol was progressively adjusted to optimize patient response. The specific protocol applied is presented in Figure 1.

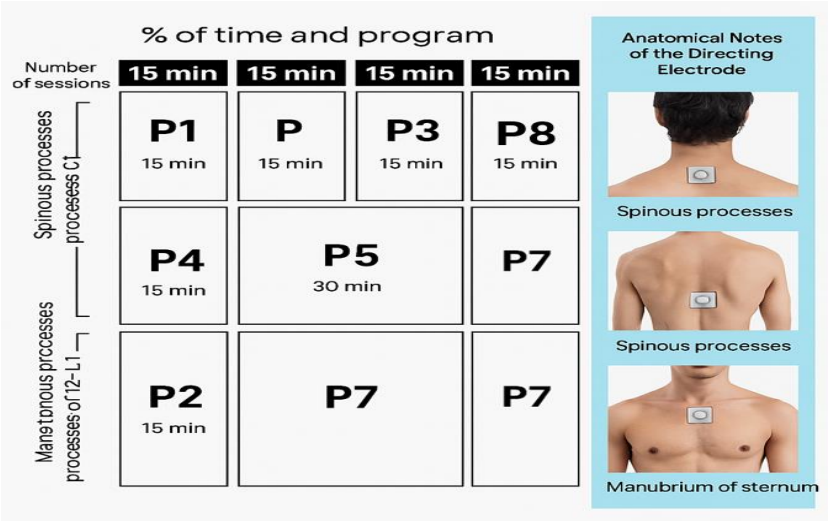
Initially, the first phase comprised three sessions aimed at acclimating the patient to stimulation, improving sleep quality, and preventing adverse effects. Specific programs (programs 1, 3, 7, and 8) were used for 15 minutes each, with the directional electrode placed at the C6/C7 level.

The second phase lasted four sessions and focused on addressing fatigue in the lower limbs, particularly targeting pelvic stabilizer muscles to improve gait. Simultaneously, this phase aimed to influence sympathetic urogenital innervation to regulate neurogenic bladder activity. During this stage, programs 4, 5, and 7 were used, with

increased emphasis on program 5 (30 minutes), while the other two were applied for 15 minutes each.

In the third phase, corresponding to the remaining eight sessions, each session began with program 2 for 15 minutes to stimulate the ventral branch of the vagus nerve. The primary focus was then placed on program 7, applied for 45 minutes, with the aim of modulating the autonomic nervous system, increasing vagal tone, and activating ascending cholinergic anti-inflammatory pathways.

Fig. 1. Distribution of programs used.



Instruments

The variables assessed in this study were measured before and after the intervention. The following instruments were used:

• Sleep quality: The Pittsburgh Sleep Quality Index (PSQI) was employed. This questionnaire includes 24 items generating seven components: subjective sleep quality, sleep latency, sleep efficiency, sleep duration, sleep disturbances, daytime dysfunction, and use of sleep medication. Total scores range from 0 to 21, with scores of 5 or less indicating poor sleep quality [15].

•Heart rate variability (HRV): The WeCardio® device (Borsam Biomedical Instruments Co., Ltd) was used to measure HRV through electrocardiogram (ECG) recordings. It assesses key indices such as Standard Deviation of Normal-to-Normal intervals (SDNN) and Root Mean Square of Successive Differences (RMSSD), which reflect parasympathetic nervous system activity. The device generates a comprehensive report on the individual's heart rhythm.

• Urinary incontinence: The International Consultation on Incontinence Questionnaire – Urinary Incontinence Short Form (ICIQ-UI SF) detects urinary incontinence across various clinical contexts and evaluates symptom severity and its impact on quality of life [16]. Scores range from 0 to 21, with any score above 0 indicating a diagnosis of urinary incontinence.

• Fatigue: The Modified Fatigue Impact Scale (MFIS), a multidimensional tool consisting of 21 items grouped into physical, cognitive, and psychosocial domains, was used. Total scores range from 0 to 84, with a cut-off score of 38 indicating the presence of significant fatigue [17].

Statistical Analysis

Data analysis and coding were performed using the Jamovi statistical software, version 2.4.14. Descriptive analyses of the study variables were conducted according to the research objectives. Additionally, comparative analysis of quantitative variables was carried out to assess statistical significance.

Ethics

All participants provided written informed consent prior to enrollment. Participant assessment and rights were protected throughout the study. The study protocol was approved by the Clinical Research Ethics Committee, in accordance with the Declaration of Helsinki.

RESULTS

Sample

Nine participants (n = 9) were initially included in the intervention group. After three weeks, one participant was excluded for not meeting the inclusion criteria, resulting in a final sample of eight participants (n = 8).

Sociodemographic Variables

The mean age of the participants was 47.1 years (SD = 5.64), with a maximum of 58 years and a minimum of 41 years. Regarding gender distribution, of the eight patients, three (37.5%) were women and five (62.5%) were men.

Half of the participants (50%) had relapsing-remitting multiple sclerosis, three participants (37.5%) had the primary-progressive form, and one participant (12.5%) had the progressive-relapsing form. The mean time since diagnosis was 11.1 years (SD = 7.40), with a range from 1 to 22 years, and a median of 13.5 years.

Additionally, comorbidities were six participants present (75%).

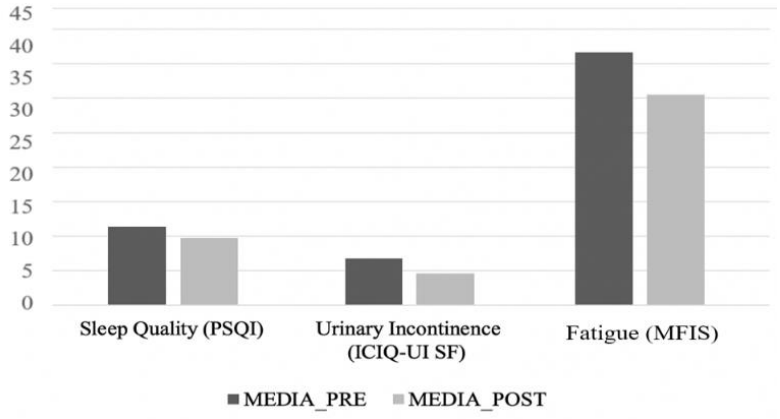
Global Data

Regarding sleep quality, intragroup comparisons were performed between pre- and post-treatment scores. The data met the assumption of normality; therefore, a paired Student's t-test was used. The p-value was 0.020 ($p < 0.05$), indicating a statistically significant difference. The mean PSQI score decreased from 10.88 at baseline to 9.38 after the intervention.

As for urinary incontinence, although the results indicated clinical improvement, the changes were not statistically significant ($p = 0.584$). The mean score decreased from 6.38 at baseline to 5.00 at the end of treatment.

In terms of fatigue, the intragroup analysis also met the normality assumption; thus, a paired Student's t-test was used, yielding a p-value of 0.215 ($p > 0.05$). While the difference was not statistically significant, clinical improvement was observed. The mean MFIS score decreased from 41.4 to 34.6 following the neuromodulation sessions. The minimum score dropped from 10 at baseline to 1 post-treatment, while the maximum score decreased from 79 to 74.

Fig. 2. General data of all participants before and after the intervention.



Case-by-Case Descriptions of the Intervention Effects

Case 1

53-year-old man, primary progressive multiple sclerosis, diagnosed two and a half years ago.

- Start of treatment: poor sleep quality (takes Deprax), wakes up several times at night and has difficulty falling back asleep. Frequent episodes of urinary incontinence before neuromodulation.

- Associated symptoms: fatigue and generalized pain.

- Comorbidities: celiac disease, unbalanced blood pressure, and anxiety.

- During and after the intervention: gradual improvement in sleep quality; able to sleep longer periods, sometimes uninterrupted. Fewer episodes of urinary incontinence and better control of urination. (Table 1).

Table I Descriptive Data For Case 1

	Initial Evaluation	Final Evaluation
PSQI (max. 21)	12	11
HRV	38 ms	32 ms
ICIQ-UI SF (max. 21)	10	11
MFIS (max. 84)	57	51

Case 2

46-year-old man, primary progressive MS, diagnosed more than five years ago.

- Start of treatment: fair sleep quality; physical activity helps induce sleep. Difficulty returning to sleep after waking.

-Associated symptoms: dizziness, tingling, lack of concentration, urinary incontinence, coordination issues.

- During and after the intervention: easier to fall back asleep after night wakings; perceived improvement in sleep quality.

Table II Descriptive Data For Case 2

	Initial Evaluation	Final Evaluation
PSQI (max. 21)	7	5
HRV	208 ms	78 ms
ICIQ-UI SF (max. 21)	0	0
MFIS (max. 84)	32	22

Case 3

43-year-old woman, relapsing-remitting MS, diagnosed 16 years ago.

- Start of treatment: poor sleep, trouble falling asleep, few hours of rest. Mild headache and malaise after initial sessions.

- Associated symptoms: fatigue, coordination issues.

- Comorbidities: endometriosis (uses hormonal IUD).

- During and after the intervention: increased sleepiness in the afternoon post-treatment; better perceived sleep quality despite short sleep duration.

Table Iii Descriptive Data For Case 3

	Initial Evaluation	Final Evaluation
PSQI (max. 21)	14	10
HRV	87 ms	33 ms
ICIQ-UI SF (max. 21)	4	4
MFIS (max. 84)	38	23

Case 4

58-year-old man, progressive-relapsing MS, diagnosed 15 years ago.

- Start of treatment: normal sleep quality due to sleep apnea (uses CPAP). No incontinence or fatigue.

- Associated symptoms: balance issues.

- Comorbidities: sleep apnea.

- During and after the intervention: no significant changes in sleep, incontinence, or fatigue.

Table Iv Descriptive Data For Case 4

	Initial Evaluation	Final Evaluation
PSQI (max. 21)	4	4
HRV	206 ms	335 ms
ICIQ-UI SF (max. 21)	0	0
MFIS (max. 84)	24	14

Case 5

45-year-old man, relapsing-remitting MS, diagnosed one year ago.

- Start of treatment: good sleep quality (takes Mirtazapine), reports some urinary incontinence.

- Associated symptoms: fatigue, gait instability.

-Comorbidities: cardiac (anterior left fascicular block, incomplete right bundle branch block).

- Important note: began fampridine for gait issues 1.5 months before NESA; reports side effects including worsened incontinence and poor sleep.

- During and after the intervention: increased episodes of fecal and urinary incontinence, worsened sleep due to more nighttime awakenings.

Table V Descriptive Data For Case 5

	Initial Evaluation	Final Evaluation
PSQI (max. 21)	9	8
HRV	57 ms	83 ms
ICIQ-UI SF (max. 21)	10	13
MFIS (max. 84)	25	42

Case 6

41-year-old woman, primary progressive MS, diagnosed 14 years ago.

- Start of treatment: good sleep quality; recent dizziness returning after remission. Reports incontinence for two years.

-Associated symptoms: knee recurvatum, right hip discomfort.

- Comorbidities: hypertension.

- During and after the intervention: increased daytime sleepiness, improved perceived rest and reduced fatigue. Better urinary control during the day; nocturnal awakenings persist.

Table Vi Descriptive Data For Case 6

	Initial Evaluation	Final Evaluation
PSQI (max. 21)	6	6
HRV	17 ms	28 ms
ICIQ-UI SF (max. 21)	17	7
MFIS (max. 84)	10	1

Case 7

47-year-old man, relapsing-remitting MS, diagnosed 22 years ago.

- Start of treatment: poor sleep quality, frequent urinary incontinence. Mild discomfort and perceptible current after first session.

- Associated symptoms: fatigue, malaise, numbness, cramps, paresthesia (right hand, ulnar nerve).

- Comorbidities: depression, lymphopenia, folic acid deficiency, drowsiness.

- Important note: medication changes for coexisting conditions during NESA sessions.

- During and after the intervention: continues sleep difficulties but falls asleep faster; improved fatigue and attention.

Table Vii Descriptive Data For Case 7

	Initial Evaluation	Final Evaluation
PSQI (max. 21)	16	13
HRV	52 ms	60 ms
ICIQ-UI SF (max. 21)	10	5
MFIS (max. 84)	66	74

Case 8

44-year-old woman, relapsing-remitting MS, diagnosed 13 years ago.

- Start of treatment: very poor sleep quality, difficulty returning to sleep. No urinary incontinence. Headache after fourth session.

- Associated symptoms: fatigue, balance issues, generalized pain.

- Comorbidities: hypertension, asthma, atopic dermatitis.

- During and after the intervention: easier to fall back asleep, fewer nighttime awakenings, improved perceived sleep quality despite fewer hours of sleep.

Table Viii Descriptive Data For Case 8

	Initial Evaluation	Final Evaluation
PSQI (max. 21)	19	18
HRV	45 ms	72 ms
ICIQ-UI SF (max. 21)	0	0
MFIS (max. 84)	79	50

DISCUSSION

The results of this case study, in which non-invasive NESA neuromodulation was applied to patients with multiple sclerosis, have shown that the treatment protocol used was effective in significantly improving sleep quality. From a subjective perspective, participants reported enhanced sleep quality. Although they did not necessarily sleep longer, they felt more rested and experienced less fatigue compared to the beginning of the intervention.

A recent 2023 study supports these findings, demonstrating that the application of non-invasive NESA neuromodulation in patients with multiple sclerosis improves sleep quality without causing discomfort during treatment, thereby contributing to enhanced quality of life [18].

Regarding neurogenic urinary incontinence, although no statistically significant efficacy was observed, clinical improvement was reported. This could be attributed to the small sample size. As the intervention progressed,

patients reported better daytime urinary control and reduced nocturia. However, one notable case (case 5) experienced increased fecal and urinary incontinence and worsened nocturia despite receiving NESA neuromodulation, likely due to concurrent treatment with fampridine.

Recent literature indicates that approximately 10% of individuals with multiple sclerosis may exhibit bladder dysfunction from the early stages of the disease, and around 80% will develop neuro-urological symptoms within 10 years of diagnosis [19]. Hence, there is a critical need to explore alternative therapies for managing this symptom, which significantly affects quality of life. Some studies have proposed percutaneous tibial nerve stimulation (PTNS) as an effective alternative for treating overactive bladder symptoms in MS. Additionally, recent work by Contreras-Polo et al. [18] presents NESA microcurrents as a non-invasive approach to modulate neurogenic bladder symptoms, demonstrating improvements in urinary incontinence.

With respect to fatigue, although the results were not statistically significant, most participants perceived an improvement. Several patients reported a reduction in fatigue and a greater sense of energy, while others stated they experienced no notable change but did not feel worse. Since up to 80% of MS patients experience fatigue—an issue that affects daily functioning—a 2020 study has shown that regular physical exercise significantly reduces fatigue. Therefore, physical activity should be an integral part of rehabilitation programs for these patients [20]. NESA neuromodulation may serve as a complementary intervention to enhance fatigue management. For instance, a recent study by Medina-Ramírez et al. [21] demonstrated that combining NESA treatment with regular sports activities (training, games, and rest periods) produces positive outcomes.

Regarding heart rate variability (HRV), SDNN, and RMSSD, although statistical significance was not achieved, favorable trends were observed. HRV increased after neuromodulation, suggesting improved parasympathetic function and reduced heart rate. SDNN also increased, indicating disruption in internal homeostasis, potentially linked to systemic inflammation. RMSSD values decreased slightly post-intervention, though still reflected a high vagal tone and an imbalance in the autonomic nervous system.

Due to the lack of statistically significant differences in this and other studies, it has been suggested that HRV and related parameters should be analyzed considering participant age. Proper age-adjustment is needed to distinguish whether observed changes stem from MS pathophysiology or from aging itself [22].

It is also important to note that Ocrelizumab, a common treatment for MS symptoms, is administered intravenously every 24 weeks. Post-marketing studies have reported that it is associated with serious herpes virus infections, which are now recognized as complications of the drug [23]. In contrast, NESA neuromodulation emerges as a non-invasive alternative capable of improving sleep quality, neurogenic urinary incontinence, and pain in MS patients, without such adverse effects [18].

Importantly, this observational study is only the second worldwide to examine the use of non-invasive NESA neuromodulation in multiple sclerosis patients. Despite the symptom variability among individuals, this technique has proven once again to be a promising therapeutic complement for enhancing quality of life. Notably, it is non-invasive and comfortable for patients, facilitating adherence and individualized application.

However, this study has some limitations, such as a small sample size, constrained by the time allocated for an undergraduate thesis. Also, HRV evaluation would be more effective if stratified by age. Additionally, the demographic questionnaire should have included more detailed information on patient medications. Future research should thus focus on larger samples and include stricter inclusion criteria based on medication use or MS subtype.

CONCLUSION

This study has demonstrated that the application of non-invasive NESA neuromodulation significantly improves sleep quality in patients with multiple sclerosis. Clinically, patients also showed improvements in fatigue, heart rate variability, and control of neurogenic urinary incontinence. However, as these findings were not statistically significant, further research is needed to confirm and expand upon these results.

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