Efficacy of NESA Non-Invasive Neuromodulation in Patients with Post-Traumatic Cervicalgia

Mónica Bonilla-Eizaguirre[1], Montse Martín[1], Andrea Hernández-Pérez[2]*, Martín Vílchez-Barrera[2], Raquel Medina-Ramírez[3], Aníbal Báez-Suárez[2]

[1]Activa Mutua, Spain

[2]University of Las Palmas de Gran Canaria, Las Palmas, Spain.

[3]University of Atlántico Medio, Las Palmas, Spain

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ABSTRACT

Injuries to the cervical spine from in-itinere traffic accidents result in significant healthcare, labor, and indemnity costs. The treatment of potential functional repercussions represents a significant challenge, with symptoms frequently resulting in the prolongation of therapies. The objective of the study was to evaluate the efficacy of the NESA non-invasive neuromodulation in the treatment of cervical spine injuries. The device employs superficial microcurrents to modulate the autonomic nervous system, thereby promoting relaxation, vasodilation, and muscle nutrition. This observational multicenter study was conducted at ACTIVA Mutua's rehabilitation facilities in Madrid, Barcelona, and Córdoba. 21 patients presenting grade I-II cervical whiplash, as per the Foreman and Croft classification, were evaluated using the Biomek biomechanical analysis system before and after the intervention, which comprised 14 days of NESA neuromodulation with active exercise. Pain and cervical disability questionnaires were administered to assess subjective outcomes. Results demonstrated a reduction in cervical mobility limitations and the onset of pain and disability within 14 days. A statistical analysis of mobility data (initial assessment vs. evolutionary control) revealed an increase in mobility in the four movements: flexion, extension, lateral flexion, and rotation. In relation to the values of the questionnaires, a decrease in cervical pain and disability was observed.

Keywords: Cervical pain, whiplash injury, electrotherapy, neuromodulator

INTRODUCTION

In the workplace, cervical pathology derived from in-itinere traffic accidents, which is to say, because of the worker's journey to or from their place of work, constitutes a considerable proportion of the overall accident rate and represents a significant expense in terms of health, labor and compensation. One of the most prevalent diagnoses in the context of traffic accidents is post-traumatic cervical pain resulting from a cervical sprain [1]. This diagnosis accounts for up to 70% of the assessments requested by forensic medical services in the context of a traffic accident [2].

The provision of a precise evaluation and medical attention is of paramount importance for a favorable response to treatment and lesion stability. The assessment protocol facilitates the precise determination of initial injuries and the formulation of a prognosis for the injured. Additionally, it serves as a tool for evaluating the evolution of the clinical picture. The Croft Whiplash Treatment Guidelines employ a five-grade severity classification system to categorize the trauma and specific lesion characteristics of patients. The severity of the injury is classified into five levels, with level 5 representing the most severe injury and requiring surgical intervention. Levels 1 and 2 are the least severe, referring to neck pain with no or minimal limitation of motion and without neurological symptoms [3].

Electrotherapy is a physiotherapy treatment that is customized according to the specific circumstances of each patient. It is a form of treatment that is continuously evolving. New treatments, such as NESA microcurrents,

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employ neuromodulation that acts within the autonomic nervous system (ANS) through surface application using physiological frequencies [4]. This treatment modality stimulates the parasympathetic autonomic nervous system, increasing relaxation and favoring vasodilation and nutrition of the musculature. This relieves muscular tension and pain, effectively enhancing other treatments [4].

The utilization of NESA non-invasive neuromodulation techniques has demonstrated efficacy in improving sleep quality [5–7]. Subsequently, an improvement in sleep quality facilitates muscular recovery and pain management in patients with diverse musculoskeletal pathologies [8,9].

The application of NESA non-invasive neuromodulation in various fields has demonstrated its efficacy in improving sleep quality [5–7], muscle recovery, and pain control in patients with diverse neurological pathologies, including multiple sclerosis [7], as well as in pediatric conditions such as infantile cerebral palsy [10]. Additionally, NESA has been shown to facilitate the recovery of fatigue and muscle condition in elite athletes [5,6].

In contrast to other treatments, such as pharmacological traditional approaches, microcurrents have demonstrated superior results over time, both in the long term and after the conclusion of treatment. This can benefit not only the overall health of patients, due to the multiple purposes of neuromodulation, which not only focuses on the physical pain of the lesion but also addresses numerous other factors, but also the reduction of secondary symptoms derived from pharmaceuticals [4,11]. Furthermore, the treatment is not contingent on the involvement of a professional, thereby enabling its administration without the constant input of a qualified individual. This renders it a straightforward intervention to be incorporated into a healthcare facility or a mutual insurance plan.

In healthcare centers, cervical pathology represents a significant proportion of patients treated with traditional physiotherapy modalities, including therapeutic exercise [12] and manual techniques [13]. However, there is potential to enhance the efficacy of these treatments by targeting the autonomic nervous system through NESA non-invasive neuromodulation. This approach could integrate efficiency, effectiveness, and efficiency into the operational framework of healthcare centers, while also facilitating patient improvement.

Considering the aforementioned rationale, the principal aim of this study is to assess the efficacy of NESA microcurrents in patients presenting with cervical pathologies resulting from occupational road traffic accidents. Consequently, quality of life, recovery and potential side effects will also be assessed. The NESA non-invasive neuromodulation will demonstrate significant efficacy in modulating the autonomic nervous system through the application of superficial microcurrents, in patients with cervical pathology.

MATERIALS AND METHODS

Design of the Study

This observational study employs a quasi-experimental design, with an intervention group in different centers of the same clinic. All participants underwent NESA microcurrent treatment and were evaluated prior to the intervention and 14 days following the conclusion of treatment. The objective was to observe the results after the treatment and rest period. To be included in the study, participants were required to have sustained a traffic accident on their way to or from work and to have a Foreman and Croft Classification grade I-II neck injury rating [3].

This design is based on the determination of cervical injuries in traffic accidents when applying the current legislation for the assessment of damage. Similarly, the correlation between the patient's reported symptoms and the clinical picture of those affected is analyzed using questionnaires on cervical pain and disability. The relationship between these symptoms and the type of treatment received is also investigated.

Sample

The participants were patients who had sustained injuries in a road traffic accident while traveling to and from their place of work. Patients who met the pre-established inclusion criteria were selected for the purposes of prognostic and evolutionary evaluation. The inclusion criteria were as follows:

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- The informed consent form must have been signed.

- The patient must be at least 18 years of age.

- The patient must have been diagnosed with a Foreman and Croft Classification grade I-II neck injury rating [3].

- The patient must not have any contraindications to the use of NESA microcurrents nor any history of electrical phobia.

Consequently, patients exhibiting more significant anatomical alterations were excluded from the study. Those contraindications for the use of non-invasive NESA neuromodulation that preclude participation in the study include the presence of internal bleeding, skin ulcers or wounds, acute febrile illness, epilepsy, pregnancy, and so forth.

Instruments

To measure the subjective aspects of this study, these two instruments were used:

- Visual Analogue Scale (VAS). This instrument is a pain rating scale to measure the intensity and frequency of various symptoms related to pain. It is employed for the assessment of pain intensity at the time of the biomechanical test. The measurement ruler displays the following legend: "No pain" at one end and "Maximum pain" at the other. The scale indicates agreement with a numerical scale from 0 (equivalent to no pain) to 10 (equivalent to maximum pain) [14].

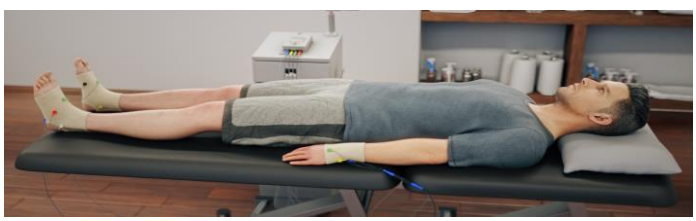
- Cervical Disability Index (CDI). This is a questionnaire designed to assess the extent of limitations experienced by patients with acute or chronic pain. The CDI has been employed in numerous scientific studies investigating patients with musculoskeletal dysfunctions, whiplash-associated disorders, and cervical radiculopathy, with the objective of measuring the level of impairment that the lesion has on the patient. The degree of disability is determined based on the score obtained in the questionnaire [15].

NESA Non-invasive Neuromodulation Treatment

NESA microcurrents represents a technique with a minimally invasive application, oriented towards the modulation of physiological functions through electrical stimulation and the stimulation of the ANS. The technique employs a low-frequency oscillating microcurrent, with a range of 1.3 Hz to 14.28 Hz. The intensity of the microcurrent is below 0.9 milliamps, and the potential difference is maintained and can be controlled by the in-dividual administering the device, within a range of ±3 V and ±6 V.

The treatment is comprised of a system of 24 semi-electrodes, strategically placed on the body to facilitate the delivery of electrical stimulation to the ANS. The electrodes are positioned in the hands and feet via the use of gloves and socks, with six electrodes per limb (Fig. 1). The circuit is completed through the utilization of a directional electrode, which is a grounding electrode positioned in the desired location for the specific treatment. The coordination of impulses across the 25 electrodes, in conjunction with the ultra-low electrical parameters of the microcurrent, enables comprehensive modulation of physiological autonomic responses throughout the body. The objective of this technique is to enhance therapeutic outcomes by leveraging the body's intrinsic electrical signaling pathways in a precise and targeted manner, thereby optimizing the body's intrinsic healing mechanisms throughout the autonomous nervous system [4].

Fig. 1. Positioning of the anklets and gloves with the electrodes attached.



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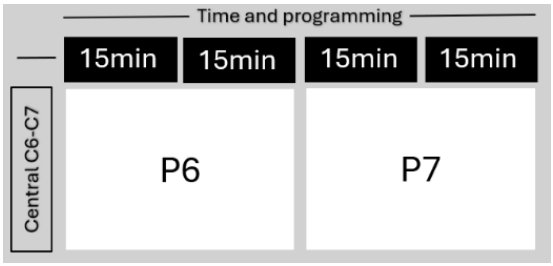
Procedure

The initial phase of the intervention entailed the dissemination of information and the procurement of written consent from all participants. Once this had been completed, the subjective questionnaires were administered to obtain the initial evaluation prior to the commencement of treatment. Subsequently, biomechanical assessments were conducted at the Activa Mutua Biomechanics Unit. This process facilitates the preliminary assessment, which will then be repeated for the purpose of monitoring progress.

Once the patient has undergone an initial assessment, an individualized rehabilitation program is initiated. This is designed in accordance with the results obtained in the preliminary evaluation and incorporates electrotherapy via superficial neurostimulation with microcurrents (NESA). The aim of incorporating this system is to provide an adjunctive treatment to assist in reducing pain and stiffness, thereby facilitating the early introduction of kinesitherapy in patients with cervical sprains resulting from traffic accidents involving whiplash injuries.

The treatment regimen consisted of sixty-minute sessions, during which Programs 6 and 7, each comprising thirty minutes of treatment, were utilized as the initial and final treatment, respectively (Fig. 2). The directing electrode was positioned in the corresponding anatomical region, which was identified as C6/C7. The number of sessions varied between six and 16, contingent on the estimated duration of the patient's treatment, as authorized by the insurance provider. Consequently, the sample size differed across patients.

Fig. 2. Distribution of programs used.



Furthermore, patients are instructed to perform specific self-assisted cervical active kinesitherapy with the objective of enhancing dynamic joint control. Information is provided on postural correction and control, both during the performance of the kinesitherapy and throughout the remainder of the day, including nocturnal periods. The objective is to minimize capsuloligamentous stress.

Statistical Analysis

To perform the statistical analysis of the mobility parameters and the scores on the questionnaires, a t-test was conducted for related samples, comparing the values obtained in the initial assessment and those obtained in the evolutionary control. Spearman's correlation coefficient was employed to examine the relationship between the mobility variables and the results of the questionnaires, as well as to assess the correlation between initial mobility and the number of rehabilitation sessions. The statistical analysis was conducted using the IBM SPSS Statistics software [16].

Ethics

All the participants provided a written informed consent prior to being assigned to a group. The assessment and the rights of all participants were protected. The Clinical Research Ethics Committee approved the study’s observational procedures.

RESULTS

Sample

A total of 21 patients were included in the study, of whom one was excluded on the grounds of non-cooperation during the tests. The demographic characteristics of the sample are presented in Fig. 3.

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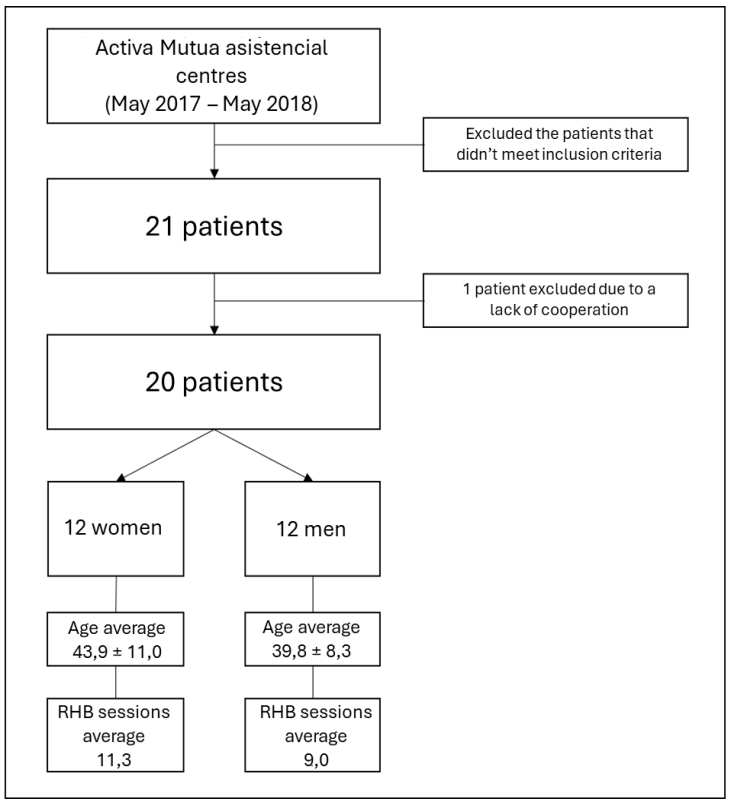
Fig. 3. Study flowchart. Sample characteristics.



Cervical Pain and Disability Characteristics

Regarding the pain variable, the sample exhibited a statistically significant reduction (p=<0.001) in pain intensity, as measured on the VAS scale, by 2.3 points. Furthermore, the cervical disability perception exhibited a notable decline, with a statistically significant difference (p=<0.001) of 11.4 between the initial assessment and the post-treatment and post-rest period assessment.

Cervical Mobility

The statistical analysis of the mobility data (initial assessment versus evolutionary control) revealed a significant increase in mobility in all four movements: flexion, extension, lateral flexion, and rotation (Table 1).

Table I. Discrepancies Between the Initial and Final Versions of The Results in Mobility

Movement	Differences between means	Significance
Flexion	6.1 º (*)	0.026
Extension	6.7 º (*)	0.011
Lateral flexion	9.7 º (*)	0.011
Rotation	23.15 º (*)	0.003

*Bilateral significance <0.05

Correlation

A negative correlation between pain and mobility is observed in three of the four movements (extension, lateral flexion and rotation). There is a positive correlation between the two questionnaires. The results are presented in Table 2.

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Table II. Correlations Between EVA with Mobility and EVA with DCI

Movement	Correlation	Significance
Flexion	-0.062	0.705
Extension	-0.438 (*)	0.005
Lateral flexion	-0.469 (*)	0.002
Rotation	-0.596 (**)	<0.001
CDI	0.577 (**)	<0.001

*Bilateral significance <0.05

** Bilateral significance <0.001

Finally, the correlations between initial mobility and the number of rehabilitation sessions demonstrate a significant inverse correlation for extension and rotation movements (Table 3).

Table III. Correlations Between Starting Mobility and Number of Sessions

Movement	Correlation	Significance
Flexion	-0.259	0.270
Extension	-0.444 (*)	0.050
Lateral flexion	-0.233	0.323
Rotation	-0.601 (*)	0.005

*Bilateral significance <0.05

The results pertaining to the cervical motion analysis, the score obtained in the VAS and CDI questionnaires, as well as the number of rehabilitation sessions performed are presented in Table 4 for reference. The mean value of the initial assessment and the sub-sequent control assessment are presented in Fig. 4.

Figure 4. Graphic representation of maximum values, statistical means (orange lines), and standard deviation (error bars).

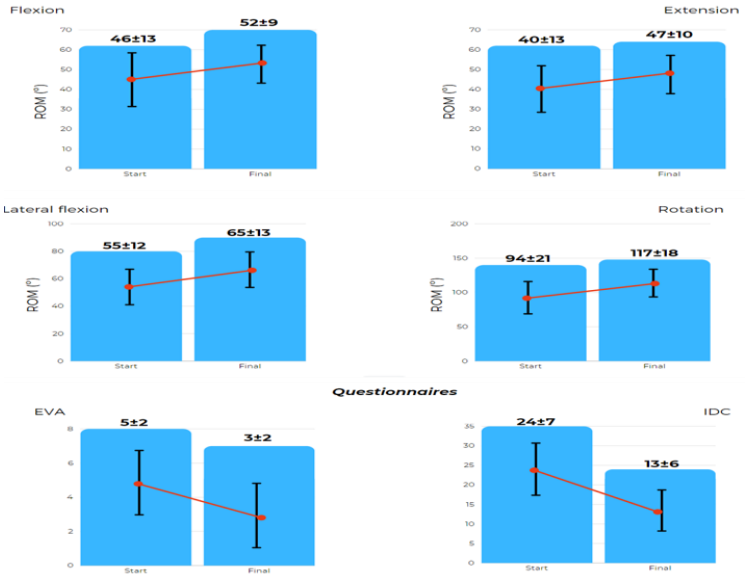

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Table IV. Initial Values and Evolutive Control of Cervical Movement, Questionnaires Scores and Number of Sessions

ID	Mobility								Questionnaires				Number of sessions
	Flexion		Extension		Lat. flexion		Rotation		EVA		IDC		
	1st	2nd	1st	2nd	1st	2nd	1st	2nd	1st	2nd	1st	2nd	
W1	35	57	50	55	58	86	114	142	5	1	19	3	6
W2	32	45	36	43	46	66	97	134	3	1	23	11	
W3	45	58	27	35	57	65	90	115	5	2	26	22	16
W4	48	53	46	46	57	66	126	118	6	5	27	14	12
W5	66	72	64	55	80	91	139	145	2	2	23	10	5
W6	60	58	49	43	69	85	106	109	2	2	16	7	6
W7	47	54	56	66	57	66	109	130	4	2	24	7	6
W8	48	46	32	44	66	70	102	109	4	1	24	13	10
W9	59	69	52	54	55	73	55	147	4	1	23	13	13
W10	25	44	31	51	59	75	75	124	7	4	15	8	15
W11	49	46	44	40	61	64	100	117	3	1	14	12	13
W12	40	42	28	57	39	72	93	131	3	0,5	19	6	12
W13	14	46	39	60	49	51	102	120	8	5	29	10	11
W14	55	65	43	62	56	70	85	139	6	5	23	16	12
W16	22	17	33	29	45	44	68	57	7	7	21	15	11
W17	63	63	31	34	39	45	83	85	7	3	34	11	11
W18	64	43	51	50	70	62	119	110	7	4	33	19	9
W19	47	51	41	46	54	57	100	129	4	3	35	24	9
W20	55	55	38	35	51	37	103	89	5	4	36	25	10
W21	39	51	9	28	34	51	61	88	7	4	15	8	9

DISCUSSION

In all cases, an increase in cervical mobility was observed in the evolutionary control with respect to the initial evaluation, irrespective of the number of sessions applied. Moreover, the coefficient of variation of the results was lower, indicating greater regularity in the cervical movement pattern. Furthermore, a reduction in pain and disability was observed at the conclusion of the rehabilitation program.

A negative correlation between mobility and pain was observed in all patients. A re-duction in pain perception is associated with an increase in range of motion, and vice versa. Biomechanical testing enables the acquisition of objective data for the assessment of process evolution. Such evaluations are useful for measuring the increase in mobility that occurs as pain decreases and for assessing the extent of remaining limitations.

A correlation was observed between the cervical pain and disability questionnaires, indicating a similar evolutionary trend. Both questionnaires were therefore deemed useful tools for measuring the subjective manifestations of patients. A reduction in pain levels is accompanied by an improvement in function, as evidenced by the results of the cervical disability questionnaire.

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In general, the deficit in cervical range of motion identified in the initial biomechanical evaluation is associated with the patient's subjective perception of a greater degree of pain and disability. As a result, the evolutionary process is more prolonged. In our study, patients exhibiting deficits in extension and rotational mobility were observed to require the longest rehabilitation period. This finding is consistent with those of other studies in which more than 10 sessions of NESA treatment were performed [5–7,10,17]. It demonstrates that the more severe the symptoms or variables, the greater the number of treatment sessions required. However, the results of this study are noteworthy in that six sessions of NESA microcurrent treatment yielded significant outcomes, indicating that the type of patient, the severity of the injury, and the combination of NESA neuromodulation with exercise can enhance its efficacy. As a result, subsequent investigations are already being conducted in analogous centers, combining the center's exercise protocols with non-invasive neuromodulation (NESA) (clinical trial registration NCT06134999).

This work represents a pioneering approach to the treatment of cervical pathology, integrating the neuromodulation of the autonomic nervous system (using NESA micro-currents) with a structured program of kinesitherapy exercises. This demonstrates the efficacy of the approach and its compatibility with a range of treatments in health centers, including those funded by mutual insurance companies. Furthermore, the outcomes observed following the improvement of between six and 16 sessions indicate that this approach may offer a cost-effective treatment option. It is integrated into the standard treatment plan, necessitating only the initial programming of the device (approximately five minutes) and no subsequent professional involvement. This is accompanied by an improvement in pain and disability. This could be a significant consideration for clinics and insurance companies, as it allows for the integration of NESA neuromodulation without additional expense, while also aligning with the primary objective of improving patient outcomes.

The present study is limited by the small sample size, which precludes differentiation of the groups according to factors that may influence prognosis, such as previous medical history and other variables (e.g., history of cervical pathology, dizziness, anxiety). Enlargement of the sample would allow for such differentiation. The total number of physical therapy sessions documented in the present study was less than that reported in other scientific studies investigating posttraumatic cervicalgia. It would be advantageous for future studies to consider the inclusion of a neurostimulation system, which has the potential to reduce pain and improve well-being, thus facilitating the early initiation of active kinesitherapy. Additionally, this study presents a sample with sessions of disparate amounts, despite the use of identical protocols and electrical parameters. This is due to the specific circumstances and context of a mutual-type clinic that is dependent on patient sessions and the contracted insurers. Although this is a methodological limitation, it is reflective of the reality of health systems of this type. Furthermore, it is essential to conduct research in real-world settings that mirror the current system. It is recommended that future studies employ a control group of patients who have not undergone neuromodulation, while ensuring that all relevant ethical considerations are met. This will facilitate a more precise evaluation of the contribution of the neurostimulation system to functional enhancement.

CONCLUSION

This initial study demonstrates that NESA non-invasive neuromodulation is a treatment that can be readily incorporated into the mutual health insurance system. It produces notable outcomes in the management of cervical pain, mobility, and disability. It can be combined with other therapeutic modalities and can be readily adapted to the protocols governing the provision of care within mutual health insurance systems.

The positive correlation between biomechanical mobility assessments and the results of pain and disability questionnaires provides further evidence that both assessment methods are valuable tools for healthcare professionals in the treatment of post-traumatic cervicalgia patients and in the development of treatment plans.

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