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Influence of Constraint-Induced Movement Therapy Associated with Ziclague® Phytotherapic in Chronic Hemiparetics

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Abstract

The study aimed to verify the influence of Constraint-Induced Movement Therapy associated with the Ziclague® herbal medicine on spasticity, functionality in the upper paretic segment and quality of life of chronic hemiparetics. An experimental, longitudinal, prospective and quantitative study was carried out, with a sample consisted of six chronic hemiparetic volunteers with mean age of 50 ± 13 years, submitted to a modified protocol associated with the bioproduct Ziclague® during 24 sessions, 60 minutes each, twice a week on alternate days and assessed before, during and after the 24 sessions, by the Modified Ashworth Scale, Fugl-Meyer Motor Assessment and Specific Quality of Life Scale for stroke. The results revealed a significant improvement ($p \leq 0.05$) in the spasticity of the pronators and finger flexors among the phases pre-treatment and after 24 sessions, as well as an improvement in the motor function of the affected upper limb between the pre-treatment and after 24 sessions and among 12 sessions and 24 sessions, and a significant improvement in quality of life between the pre-treatment and after 24 sessions. It was concluded that Constraint-Induced Movement Therapy associated with the Ziclague® Phytotherapic constitutes a form of effective rehabilitation in the motor function and in the modulation of the affected upper limb tonus, improving the quality of life of chronic hemiparetic patients.

Keywords: Stroke; Hemiparesis; Spasticity; Phytotherapy; Physical therapy

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Introduction

Stroke is one of the main neurological pathologies and consists in focal or global functional disorders which occur in a period of 24 hours or more [1,2]. It is part of the cardiovascular diseases group, being the most prevalent disease, corresponding to 31% of the total global mortality rate and it is estimated to remain the second largest until 2030. In Brazil it is among the main causes of death and presents high morbidity and mortality rates [3,4].

The individual can develop a set of sequels that affect the functional independence. Can be sensory-motor, sensory, cognitive, language and communication changes, making it difficult to carry out of daily life activities [5]. Hemiparesis of brachial predominance is one of the most ordinary stroke alterations with a higher incidence of lesions in the middle cerebral artery (70% of the cases). Associated with loss to upper and lower centers control of the corticospinal tract, results in spasticity, and altering the reciprocal inhibition mechanism and causing uncoordinated movements patterns [6,7].

The spasticity and paresis brachial causes limb disuse and the individual develops compensatory mechanisms that prioritize the unaffected upper limb (UL) only, triggering the unsatisfactory neuroplasticity adaptation [8]. The Constraint Induced Movement Therapy (CIMT) is a therapeutic technique that aims to overcome the non-use learned through sensory-motor rehabilitation of the paretic segment, characterized by intensive training and repetitive practices [9]. CIMT is divided into three parts: shaping procedure; task practice, associated with the restriction of healthy UL; and the transfer package that provides a behavioral contract, daily motor evaluation and home exercises[10,11].

With regards to spasticity on the chronic hemiparetic, Ziclague® is a phytotherapic bioproduct with production in spray for dermal use by Hebron® laboratory. It is constituted of essential oil of the *Alpiniazerumbet* plant, with active principles (sesquiterpenes, 1, 8 cineol and terpinen-4-ol biochemical marker: sabinene) involved in the intracellular calcium control, acting on the contractile properties of the skeletal muscle and on the possible tonus modulation, promoting relaxation of the spastic musculature [12-15].

Ziclague® has a mechanism of peripheral action that differs from most antispastic medicines and represents an advance in the supporting treatment of spasticity from neurological pathologies related to lesions in the superior motor neuron or the pyramidal tract [12].

Due to the absence of research in the literature associating CIMT protocols to the effects of Ziclague® herbal medicine, this study aimed to verify the influence of CIMT associated with the bioproduct on spasticity, motor function in upper paretic segment and the quality of life of hemipartic patients after chronic stroke.

Materials and Methods

It is an experimental, longitudinal, prospective and quantitative study, approved by the Research Ethics Committee (Res. CNS 466/12) of the National Health Council with the protocol number 07810918.3.0000.5169 and carried out at the Physical Therapy School Clinic of the University Center of Pará, from April to November 2019.

The sample consisted of 10 volunteers, with a remaining sample of 6 volunteers. It were included individuals with: chronic hemiparesis with brachial predominance; spasticity grade 3 at maximum; minimum strength grade of 3 in the upper limb affected; 10° of minimum active metacarpalangeal and interphalangeal extension and 20º of active elbow extension, considering the position of 90º of elbow flexion measured with goniometer; and score higher than 24 points in the Mini Mental State Examination [16] or considering the score used for illiterate people.

The volunteers were excluded with: any hemodynamic instability, according to the I Brazilian Guideline of Cardiovascular Prevention [17], sudden or constant headache, angina, thrombophlebitis or recent embolism, cardiac arrhythmias, valvular disorders, visual and hearing impairment that prevents to apply the protocol, recurrence of strokes, double hemiparesis, apraxias and sensory transcortical aphasia, from Wernicke and global, hypersensitivity and allergy to any of the components of the Ziclague®'s formula, through allergy testing.

After the initial screening, were collected the evaluation data before the sessions, during the sessions (after 12 sessions) and at the end of the sessions (session 24), using the assessment instruments: Modified Ashworth Scale (MAS) to evaluate the degree of the chosen muscle groups spasticity of the paretic upper segment (elbow flexors, pronators, wrist and fingers flexors) through a classification consisting of six grades with increasing order for the level of muscle tone [18]; Fugl-Meyer Motor Scale (FMA), modified to assess the degree of functional recovery of the hemiparetic patient in relation to the affected upper limb only, consisting in four domains: motor function, sensitivity, range of motion and joint pain, totaling 66 points [19]; Specific Quality of Life Scale for stroke (SQLS-Stroke) which has 12 domains (energy, family role, language, mobility, humor, personality, self-care, social role, memory/concentration, upper limb function, vision and work/productivity), with 49 items and scores from 1 to 5 for each [20].

The patients were submitted to a modified CIMT protocol associated with the application of Ziclague® on the upper limb paretic, in 24 sessions of 60 minutes each, twice a week and on alternate days, with the vital signs measured before and after each session. Before the beginning of the protocol, all the volunteers placed a positioning orthosis on the healthy segment, guaranteed restriction of the non-paretic limb [21].

All the volunteers received, 20 minutes before starting the CIMT protocol, the Ziclague® phytotherapic spray with registration at Health Ministry 1.1557.0069.002-5 (flask of 60ml), in the skin region corresponding to the muscular groups evaluated by MAS. The dosage used is indicated for hemiparetic adults (3 to 4 jets), which each jet corresponds to 0.2ml of Ziclague, with a total of 0.6 to 0.8ml in each session. According to the Federal Council of Physiotherapy and Occupational Therapy, through Judgment N° 611, 2017, considering the National Policy of Integrative and Complementary Practices, the physiotherapist can use and indication of phytotherapies/phytodrugs.

After the 20 minutes, the CIMT protocol was initiated. In each session the volunteers performed a protocol of functional tasks individually, in the order of execution: screwing on containers of different sizes; opening and closing locks; taking a 500 ml jar and serving five glasses; picking a glass and taking it to the mouth; picking a spoon and taking it to the mouth; performing the hair combing movement; cleaning the table with a sponge with circular movements; performing activities with fitting games; placing marbles and clips in a container; flip playing cards; bounce a ball on the floor; paintingvertical lines [22]. Each task was performed for 5 minutes, totaling the 60 minutes of therapy, being progressively increased the difficulty of each task as of the 12th session, such as distance, size, weight and material of the objects. In addition, the tasks included the use of all upper limb joints.

The collected data were tabulated, interpreted, processed and analyzed by means of processing in the Statistic Package for Social Sciences (SPSS) system version 24.0. Pearson's Chi-square statistical test was used for statistical analysis of the data, in order to indicate whether the observed frequencies showed a significant trend, and the Analysis of Variance test, in order to point out the significant differences between the therapy phases in the different domains of the measuring instruments. It was adopted a p-value significance level of ≤ 0.05.

Results

The **Table 1** shows that most volunteers were male; all individuals presented the right side as dominant; and most presented the right side as affected. The mean age was 50.33 ± 12.54 years and

Table 1 Description of chronic hemiparetic volunteers submitted to CIMT associated with Ziclague® phytotherapy.

Characterization	n	%
Gender		
Female	2	33,3%
Male	4	66,7%
Dominant side		
Right	6	100,0%
Left	0	0.0%
Affected side		
Right	4	66,7%
Left	2	33,3%
Lesion time		
Less than 1 year	2	33,3%
2 to 4 years	1	16,7%
5 or more	3	50,0%

injury time was 4.05 ± 3.44 years.

Table 2 shows that there was a significant reduction ($p<0.05$) in the mean values of the pronators ($p=0.008$) and finger flexors ($p=0.021$) only, between the pre-treatment and after 24 sessions, indicating that there was a significant improvement in the spasticity degree after the 24 treatment sessions.

In **Table 3** there was a significant increase ($p<0.05$) in the mean values of the FMA related to motor function only, between the pre-treatment phases and after 24 sessions ($p=0.000$) and between 12 sessions and 24 sessions ($p=0.042$), however the means of other variables did not show significant ($p>0.05$) during the treatment phases, although the values increased. Thus there was a significant increase in the degree of the volunteers' recovery only in motor function.

Table 4 shows that all SQLS-Stroke domains evaluated showed an increase in the mean score after 24 sessions, but the increase was significant ($p<0.05$), only between the pre-treatment phases and 24 sessions, for the upper extremity variables ($p=0.002$), family roles ($p=0.024$), personality ($p=0.011$), and the total SQLS-Stroke score ($p=0.011$).

Table 2 Mean values and standard deviation of the spasticity degree in the muscle groups of the affected upper limb, evaluated at three moments by the Modified Ashworth Scale (MAS).

Muscle Group	Pre-treatment	12 sessions	24 sessions
Pronators	1.8 ± 0.26	1.50 ± 0.32	1.25 ± 0.27*
Finger Flexors	1.75 ± 0.27	1.50 ± 0.45	1.25 ± 0.27*
Wrist flexors	2.00 ± 0.55	1.92 ± 0.59	1.67 ± 0.75
Elbow flexors	1.83 ± 0.61	1.50 ± 0.45	1.25 ± 0.42

* p≤ 0.05

Table 3 Mean values and standard deviation of the functionality variables of the affected upper limb, evaluated in three moments by the Fugl-Meyer Motor Assessment Scale.

FMA variables	Pre-treatment	12 sessions	24 sessions
Motor function	30.50 ± 8.34	40.83 ± 6.85	51.83 ± 5.81*+
Sensitivity	11.67 ± 0.82	12.00 ± 0.00	12.00 ± 0.00
Passive Joint Movement	20.67 ± 4.13	22.50 ± 2.07	23.17 ± 1.60
Joint Pain	14.67 ± 7.89	17.67 ± 6.98	18.17 ± 5.64

* p≤ 0.05 (pre-treatment – 24 sessions)
+ p≤ 0.05 (12 sessions – 24 sessions)

Table 4 Mean values and standard deviation referring to the quality of life of stroke volunteers, assessed in three moments by the Specific Quality of Life Scale for stroke (SQLS-Stroke).

SQLS-Stroke Variables	Pre-treatment	12 sessions	24 sessions
Self-care	15.83 ± 8.82	19.83 ± 6.55	22.83 ± 2.48
Energy	11.83 ± 4.54	11.83 ± 4.31	13.00 ± 3.10
Upper Extremity	9.50 ± 3.45	14.17 ± 4.96	19.17 ± 3.37*
Humor	17.50 ± 5.21	18.17 ± 4.17	22.83 ± 3.37
Language	17.00 ± 7.72	20.50 ± 7.04	21.67 ± 5.32
Memory/ Concentration	10.17 ± 4.36	12.33 ± 4.23	14.67 ± 0.82
Mobility	18.17 ± 6.49	20.33 ± 5.50	22.67 ± 3.39
Family Roles	8.17 ± 4.31	11.50 ± 1.23	13.00 ± 1.90*
Social Roles	11.67 ± 4.23	13.50 ± 4.72	14.67 ± 5.50
Personality	6.33 ± 4.63	10.50 ± 4.32	13.83 ± 2.04*
Work/Productivity	7.67 ± 3.39	10.00 ± 3.16	11.67 ± 2.42
Vision	14.50 ± 5.43	13.33 ± 4.08	14.83 ± 0.41
Quality of Life (Total)	147.2 ± 25.9	174.2 ± 33.4	204.83 ± 11.21*

* Differs from pre-treatment (p ≤ 0.05)

Discussion

The Ziclague® establishes a new perspective in the rehabilitation of spasticity, representing a great advance for the coadjutant treatment in the physiotherapy and stimulus factor for motor rehabilitation, causing expansion and growth of the profession [12].

In this study there was a significant reduction in pronators and finger flexors at the end of the sessions, but all muscle groups showed a reduction in the mean score during the three phases of assessment, revealing that all volunteers obtained an improvement in the spasticity degree in the affected upper limb. This improvement can be justified due to the antispasmodic properties of the extract obtained from the stem and leaves of the *Alpinia Zerumbet* plant, the main component of Ziclague®. Acts by means of its active principles in blocking muscle ryanodine receptors and L-type calcium channels, related to the regulation of intracellular calcium and the sarcoplasmic reticulum associated to the modulation of the actin-myosin complex, components of the muscle contraction mechanism [12].

The significant improvement of pronators and finger flexors can be related to the CIMT tasks proposed, as some of it requires more precise movements, coordination and dexterity to manipulate objects, according to the demands of each task.

Associated to this, the training with repeated exercises proposed by CIMT are important for the process of tonus modulation, and consequently of the spasticity. Its provide activation and recruitment of muscle motor units that had losses after neuronal injury with changes in the action potentials frequency, acting on the intrinsic properties of the neuromuscular system [23], which can justify the reduction of spasticity in muscle groups in this study.

Maia et al [14] identified, through electromyography findings, improvement in the pathological excitability of the spastic muscle group in stroke individuals compared to the healthy muscle group, using essential oil from *Alpinia Zerumbet*, corroborating with the evidence presented in this study about the effects of Ziclague® on spastic symptoms of stroke individuals.

The same was observed by Candido and Xavier-Filho [24], which applied essential oil of *Alpinia Zerumbet* on the dermal surface of the spastic muscles in children with cerebral palsy, to optimize the protocol of the imposed physiotherapeutic treatment. There was a significant reduction in muscle tone degrees in the group of the treatment compared to the other three groups with different protocols, ratifying the present findings in relation to the antispasmodic effects of the plant extract on spasticity, resulting from changes in the central nervous system.

Despite the apparent positive effect, it is necessary to carry out more in-depth and complex studies to verify and consolidate the performance of Ziclague® at the peripheral neuromotor level and the continuous use for the maintenance of tonus modulation, since in this study the application was only until the end of the last session, not being evaluated the volunteers spasticity sometime after the end of treatment. It is important to emphasize that the dosage used in the volunteers was the same indicated for adult hemiparetic patients, according to the manufacturer (HEBRON®) which consists in 3-4 jets [12].

Rocha et al [22] performed a study with chronic hemiparetic individuals who carried out 12 sessions of a modified CIMT protocol, three times a week, on alternate days, for two hours daily. It was observed an improvement in muscle tone of the paretic upper segment, in passive joint movement, in motor function of the affected upper limb and joint pain, according to the FMA scale. Its corroborates with the results of this study, which volunteers had significant recovery in the motor function between the pre-treatment phases and after 24 sessions and between 12 sessions and after 24 sessions. In addition, all domains showed an increase in the mean score, showing that there was an improvement in the functional degree of volunteers, with positive effect of joint rehabilitation therapy.

The positive effect is related to the CIMT, since it is a therapy focused on the rehabilitation of the motor function of the upper limb paretic, which performing an intensive training with specific tasks and generate motor learning by increasing the difficulty to perform the tasks. Furthermore, enables different experiences, seeking the improvement of human movement patterns and the neuroplasticity adaptation by means of neurogenesis, synaptic remodeling and functional changes in neuronal cells, and overcome the unlearned use of the affected upper segment [25-27].

Can be considerable that Ziclague® had influenced the significant evolution of motor function in the upper segment affected, as well as in the other domains, since the reduction of the spasticity by the herbal medicine results in the improvement of the reflex mechanism of reciprocal inhibition, causing an increase in motor control due to the decrease in muscle weakness and in motor coordination deficit [14,28,29].

A study conducted with 14 stroke patients ratifies the present findings. Individuals was divided in Experimental Group (EG) which performed CIMT 5 times a week, 2 hours a day, and Physiotherapy and Occupational Therapy (POT); and Control Group (CG), which carried out POT only. It was revealed that the EG, which used a containment glove on the healthy upper limb, had a better performance in occupational activities and in the affected segment functionality than the GC, concluding that CIMT is effective as rehabilitation therapy [30].

Yu et al [31] also used a modified CIMT protocol in a EG of stroke patients for 3 hours daily, for 10 consecutive days, using a containment glove in the healthy upper limb in 30% of the vigil hours, while the CG was treated with physiotherapy and occupational therapy. The results revealed that the EG showed a significant improvement in the movements of the affected UL compared to the GC, based on the Wolf Motor Function Test (WMFT) and Motor Activity Log (MAL) assessment instruments, emphasizing the CIMT effectiveness.

Nasb et al [32] presented significant results between the comparison of two groups, one that used botulinum toxin associated with CIMT (BTX-mCIMT) and another that used botulinum toxin associated with conventional therapy (BTX-ICT) in chronic stroke hemiparetic patients. The instruments used was MAS, FMA and Barthel's Index, which showed that both groups achieved significant improvement in the spasticity of the muscle groups evaluated (flexors of elbow, wrist and finger), but the protocol performed by the BTX-mCIMT group was more effective in motor function recovery of the affected upper limb and in the gain of functional independence, also ratifying the present findings.

With regard to the quality of life results, all domains of EQVE-stroke achieved a rise in the mean score at the end of the 24 sessions, with a significant improvement in relation to the upper limb, family roles and personality, showing that there was a significant increase in the quality of life of the volunteers in this study.

According to Kelly et al [33], the improvement in quality of life is not restricted to gains in motor function, but extends to the psychosocial domains. It is also essential to transfer these motor gains to daily activities, since the use of the affected arm during daily activities maximizes the quality of life, stimulating the cognitive, social relations and psychosocial improvement.

Haddad et al [34] also ratifies that CIMT is a rehabilitation therapy whose origin and principles are based mainly on behavioral psychology, improving not only motor function, but also emotional of stroke patient, which demonstrates a small, but significant, improvement of the depressive symptoms. It is in accordance with the outcome presented in this research, since the volunteers showed a motivational growth during the sessions, with better humor and dedication to the treatment, feeling more encouraged to look up an improvement in the clinical condition.

In general, it is essential to carry out physical rehabilitation in stroke patients, since the individuals present functional gains for perform daily activities and improvements in mobility, work and productivity, personal care, behavior, way of thinking, quality of life, social and family relationships [35].

Therefore, results of the therapy proposed by this study were attributed to the joint work of CIMT and the Ziclague® herbal medicine and not separately the effects of each therapy, since the Ziclague® represents a complementary treatment to the main therapy, which in this case corresponds to CIMT used associated with exercises.

Despite the results, it is important to emphasize the limitations presents in the study. During the data collection some participants abandoned the research; the researchers had difficulty in finding volunteers who fits the profile of the study, because the inclusion and exclusion criteria reduced significantly the sample, resulting in a relatively small number of participants; and the shortage of studies with Ziclague® in spastic patients made it difficult to make a critical comparison with other studies and its respective results.

Conclusion

Based on the present findings, it is concluded that the Constraint-Induced Movement Therapy associated with Ziclague® can be an effective and differential treatment in the improvement of motor function, modulation of the paretic upper limb tonus and overcoming the non-use learned, through of the training with the tasks required and the antispasmodic effects of the phytotherapic, which assist and optimize the rehabilitation process of the paretic upper limb, improving the quality of life. However, there is a need for more in-depth studies, with a larger population to be investigated, to ratify the real effects of this joint therapy.

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