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Original Article

Immediate effect of transcranial direct current stimulation combined with functional electrical stimulation on activity of the tibialis anterior muscle and balance of individuals with hemiparesis stemming from a stroke

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Abstract. [Purpose] The aim of the present study was to evaluate the immediate effects of transcranial direct current stimulation (tDCS) and functional electrical stimulation (FES) on activity of the tibialis anterior muscle (TA) and static balance of individuals with hemiparesis stemming from stroke. [Subjects and Methods] A randomized, double-blind, crossover, clinical trial conducted with 30 individuals with chronic post-stroke hemiparesis. Median frequency of electrical activity of the TA were determined using electromyography in five contractions concentrics and Static balance (body sway velocity and frequency), both before and immediately after the intervention. The participants were submitted to four 20-minute intervention protocols with 48-hour interval: anodal tDCS + sham FES; sham tDCS + active FES; anodal tDCS + active FES and sham tDCS + sham FES. Anodal tDCS was administered over C3 or C4, the cathode was positioned in the supraorbital region on the contralateral side and FES was administered to the affected TA. [Results] No significant differences among the protocols were found regarding electrical activity of the TA and static balance. [Conclusion] The results demonstrate that tDCS alone or in combination with FES had no immediate effect on electrical activity of the TA and static balance of the 30 individuals analyzed.

Key words: Hemiparesis, Transcranial direct current stimulation, Functional electrical stimulation

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INTRODUCTION

According to the World Health Organization, stroke is the third most common cause of chronic disability in developing countries[1)]. Hemiparesis (muscle weakness on one side of the body) is one of the classic manifestations of a stroke event and commonly affects the upper limb flexors and lower limb extensors[2)].

In the lower limb, the characteristic "foot drop" that occurs with this condition results from a reduction in the strength of the tibialis anterior (TA) muscle as well as spasticity of the plantar flexor musculature (triceps surae)[3)], which diminishes contact between the heel and ground, thereby affecting balance and locomotion[4)] and exerting a negative impact on functional independence[5)].

Functional electrical stimulation (FES) has been used for the treatment of motor impairment in patients with hemiparesis

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or hemiplegia[6–11]. This method consists of the depolarization of the intact motor neuron to initiate and facilitate the voluntary contraction of paretic or paralyzed muscles to produce functional movement[12]. Moreover, transcranial direct current stimulation (tDCS) is a new therapeutic modality used for the modulation of the central nervous system[13], which consists of the administration of a monophasic electrical current through two electrodes (anode and cathode) positioned strategically on the skull based on the area of the brain one wishes to stimulate[14].

In animal experimental models with cerebral ischemia, anodal tDCS administered over the injured hemisphere is reported to have significant effects related to the recovery of motor function[15]. Positive effects regarding motor recovery have also been reported in experimental studies in humans[16, 17]. Cross-sectional study of Sohn et al. [18] found an immediate significant increase in quadriceps strength and static postural stability following tDCS over the primary motor cortex of 11 individuals with hemiparesis. In the same direction, Madhavan et al.[19] found an improvement in voluntary control of the ankle in nine patients with hemiparesis during 15 minutes of anodal tDCS over the injured primary motor cortex when combined with ankle motor training. Thus, it is supposed tDCS can modulate spontaneous neuronal excitability, promoting either the hyperpolarization or hypopolarization of the resting potential of the neuronal membrane, thereby facilitating the arrival of peripheral information stemming from the therapeutic process[20, 21].

The largest benefit of tDCS may come from its use in combination with different forms of physical therapy, as this method is a way to modulate the activity of the cerebral cortex, opening a path for the enhancement and prolongation of the functional gains provided by physical therapy. It can therefore be said that stimulation evokes a change in the dysfunctional excitability pattern so that physical therapy can model the functional pattern of cortex activity with the activation of specific neural networks[22].

The aim of the present study was to evaluate the immediate effect of a single session of anodal tDCS combined with FES on electrical activity of the TA muscle and static balance in patients with hemiparesis stemming from a stroke. The hypothesis is that tDCS can potentiate the activity of the TA muscle promoted by the administration of FES, especially in the chronic phase of the disease (when it has already been installed in the mechanisms of maladaptive plasticity).

SUBJECTS AND METHODS

A randomized, sham-controlled, double-blind (patients and examiner), clinical trial was conducted following approval from the Human Research Ethics Committee of University under process number 767.866/2014. This study is registered with the International Clinical Trials Registry (ClinicalTrials.gov −NCT02389608) and all participants signed a statement of informed consent. The study was conducted in January 2016 at the Integrated Movement Analysis Lab of University Nove de Julho.

The 30 subjects (twenty-three men and seven women) who participated in this study were recruited from the physiotherapy clinic of the University Nove de Julho. The inclusion criterion was a diagnosis of hemiparesis stemming from a stroke. The exclusion criteria were a score of less than 11 points on the Mini Mental State Examination, reduced ankle mobility due to a history of fracture or the use of an ankle fixator, non-reducible foot drop, TA muscle strength <Grade 1 on the Kendall[23] scale, self-declared severe vision impairment, contraindication for use of tDCS (history of seizure or recurrent epilepsy, brain tumor at stimulation site and metallic implants in skull), skin infection at the administration site for tDCS or FES, anesthesia or hyperesthesia at FES administration site, a diagnosis of deep vein thrombosis, Alzheimer's patients, diagnosis of degenerative disease or polyneuropathy.

The tDCS was performed using the *Tct Research 1 CH tDSC Simulator model 101,* which measures 14.0 × 11.5 × 3.5 cm, weighs 350 g and is fed by two alkaline 9-volt batteries. The device has a high-precision microprocessor and a controlled direct electrical current. Stimulation was achieved with two sponge (non-metallic) electrodes moistened in saline solution (cathode: 5 × 5 cm; anode: 5 × 7 cm). The anode was positioned over either C3 or C4 (depending on the injured hemisphere) and the cathode was positioned in the supraorbital region contralateral to the anode[24]. A current of 2 mA[19] was administered for 20 minutes during cycles of standardized active contraction of the TA (six seconds of contraction and 12 seconds of rest). Sham stimulation followed the same procedures as active stimulation, but the device was only switched on for the first 20 seconds. Thus, the individuals receiving the sham procedure had the initial sensation of stimulation, but received no electrical current during the remainder of the session. This is considered a valid control procedure in studies involving tDCS[25].

FES was performed using the QUARK® FES, VIF 995 DUAL. Two self-adhesive rubber electrodes measuring 5 cm^2 were positioned −one over the motor point of the TA muscle and one immediately below the belly of the muscle. Active FES was conducted for 20 minutes with a pulse width of 250 µs, modulated at a frequency of 50 Hz and stimulation cycles of 1:2 (TON for six seconds and TOFF for 12 seconds)[26] associated with active contraction of the TA muscle during the six seconds of TON. Sham FES followed the same procedures, but the device was switched on only for the initial 20 seconds, with the current then diminished to zero. The patients were informed of the possibility of feeling a slight initial tingling that would either diminish, disappear or continue during the 20-minute session[27].

Electromyographic (EMG) activity of the TA muscle during dorsiflexion was the primary outcome and static balance was the secondary outcome, both before and immediately after the intervention protocols.

The activity of the TA was analyzed by the variable median frequency and RMS, collected by the an electromyograph

(FREEEMG® −BTS Engineering), with a four-channel conditioner module (BTS FREEEMG 100®), analog/digital converter with 16 bits of resolution, common rejection mode ratio>100 dB and 20–450 Hz band pass filter was used for the analysis of TA muscle activity. The EMG signals were amplified (gain: 2,000 fold), with wireless transmission using a sampling frequency of 1 kHz.

Each patient was instructed with regard to the execution of the movements for the evaluations and the EMG data were captured with the patient seated on a chair with knees flexed at 90° and the ankles in the neutral position[22]. After cleaning the sites with 70% alcohol, disposable self-adhesive Ag/AgCl electrodes measuring 1 cm in diameter (*Medi-Trace 200 Kendall Healthcare/Tyco*, Canada) positioned 2 cm center to center were used to capture the EMG signal of the TA muscle, following the SENIAM guidelines (Surface Electromyography for the Non-Invasive Assessment of Muscles)[28], which was not altered even after the intervention protocol.

The patient performed three maximum voluntary contractions (MVCs) of the TA muscle for 10 seconds with a two-to-three-minute rest between contractions[19]. After one minute of rest, the patient was instructed to perform five consecutive dorsiflexion movements of the foot (isontonic contraction) three times with a two-to-three-minute rest between repetitions.

The amplitude of the signal captured during isotonic contraction was analyzed based on the root mean square (RMS) after being normalized by the largest RMS obtained during the three MVCs (μmV/μV × 100: % MVC). The median frequency was estimated using the Fourier fast transform considering windows with 1,024 points and 50% overlap (Hammingwindow). The median frequency was chosen because it is an indicator of recruitment of motor units. The higher the median frequency, the greater the imput generated in each muscle fiber thus increasing the contraction factor of the muscle.

Static balance was evaluated using a force plate (Kistler model 9286BA) with a 100-Hz acquisition frequency and four piezoelectric sensors measuring 400 × 600 mm positioned at the extremities of the platform. The patient was instructed to remain in quiet standing on the force plate with feet positioned at the base of a triangle. Static balance was evaluated with eyes open (EO −gaze fixed on the horizon) and eyes closed (EC)[29]. Three 30-second readings were taken under each condition with a five-minute rest period between trials.

Movement of the center of pressure (COP) in the anteroposterior and mediolateral directions was used for the analysis of postural balance. The COP signals were filtered (Butterworth 10-Hz low-pass filter) for the subsequent calculation of the following indicators of postural control: i) mean sway velocity and ii) mean sway frequency[30]. Sway velocity in both directions was calculated based on the total distance of the movements divided by the data collection time[31]. Sway frequency was determined by the frequency band with 80% of spectral power[32, 33].

The EMG and stabilometric data were processed using specific routines developed in MathLab, version 2010b (The MathWorks Inc., Natick, MA, USA).

The statistical analysis was based on the systematic review addressing the effects of tDCS and transcranial magnetic stimulation on motor function in stroke survivors, in which the mean per study was 30 participants[16].

The order of the protocols was determined using a randomization table implemented in Excel™ by an independent researcher who did not participate in the recruitment of the patients. A crossover design was used, with a period of 48 hours respected between sessions to avoid the potential additive effect of the stimulations[18, 34] (padronized protocols on Monday, Wednesday, Friday and Sunday). At each step, the individuals were submitted to pre-intervention and post-intervention evaluations (EMG and stabilometry). The following protocols were conducted each in a single 20-minute session:

1. Active anodal tDCS + sham FES;
2. Sham tDCS + active FES;
3. Active anodal tDCS + active FES;
4. Sham tDCS + sham FES.

The participants and researchers in charge of the evaluations were blinded to the arm of treatment (active or sham stimulation). Only the tDCS operator was aware of the treatment being administrated.

Descriptive statistics (measures of central tendency and dispersion) were used for the characterization of the sample and distribution of the inferential data: mean and standard deviation for parametric variables; median and interquartile range for nonparametric variables; and frequency and percentage for categorical variables.

The Shapiro-Wilk test was used to determine the distribution of the data. Data with asymmetric distribution were log-transformed prior to analysis to negate the effects of heteroscedasticity. The stabilometric data were not normally distributed even after log-transformation and were therefore expressed as median and inter-quartile range (25% and 75%) and analyzed using nonparametric tests. The Mann-Whitney test was used for the comparison of pre-intervention and post-intervention sway velocity and frequency scores. The EMG data exhibited normal distribution (log-transformed median frequency values) and two-way repeated-measures analysis of variance (ANOVA) considering the factors time (pre-intervention and post-intervention) and groups (1, 2, 3 and 4) was used for the intergroup and intragroup comparisons with the Bonferroni post hoc test. The SPSS 20.0 program (SPSS Inc., Chicago, IL, USA) was used for all analyses and the level of significance was set to 5% ($p<0.05$) for all interactions.

RESULTS

Table 1 displays the demographic and clinical characteristics of the participants (n=30). Thirty-three patients were initially recruited, three of whom did not meet the eligibility criteria (Fig. 1).

In the analysis of the primary outcome (EMG data), no significant time vs. group interactions were found for median frequency ($F=0.85$, $p=0.44$; $\eta_p^2=0.01$) or the RMS ($F=0.24$, $p=0.86$; $\eta_p^2=0.004$) (Table 2). Moreover, no significant differences were found between the pre-intervention and post-intervention evaluations of the stabilometric data (median, inter-quartile range and effect size) (Table 3).

DISCUSSION

In the present study, the combination of anodal tDCS and active FES had no significant effect on electrical activity of the TA muscle or static balance in stroke victims with hemiparesis. These findings suggest homeostatic defense mechanisms of the central nervous system. According to Bienenstock-Cooper-Munro[35] a high level of synaptic activity may subsequently reduce any task that requires a further increase in neuronal activity[35]. Thus, the stimulus during the post-intervention EMG evaluation (which was also a motor task) may have required an increase in neuronal activity, which was already excited by the 20 minutes of stimulation, thereby causing an immediate reduction in activity[36].

However, immediate effects ($p<0.05$) from tDCS over the primary motor cortex combined with other forms of physical therapy have been demonstrated: Madhavan et al.[19] found an increase in evoked motor potential (EMP) during 15 minutes and immediately after the practice of ankle dorsiflexion combined with tDCS in nine patients with hemiparesis. Sriraman et al.[22] evaluated EMP before, during and 24 hours after tDCS combined with ankle biofeedback. Rizzo et al.[37] evaluated EMP after 10, 20, 30 and 60 minutes of tDCS combined with repetitive electrical stimulation of the median nerve in healthy individuals.

However, it is not possible to affirm whether the positive effects found in the nine stroke survivors in the study by Madhavan[19] are representative of larger populations, such as the sample employed in the present study (30 volunteers). Moreover, the trials conducted by Sriraman et al.[22], Rizzo et al.[37] and Dutta et al.[20] that involved tDCS in healthy individuals, the physiology and cortical excitability differs from individuals with a central nervous system injury. Maladaptive neuroplasticity is found in the chronic phase following a stroke. Thus, greater afferent information is required so that motor neurons surrounding the injured area can be molded to increase the number of connections and improve synaptic transmission pathways for effective motor recovery[38]. In contrast, such compositions are intact in healthy individuals[39].

Based on these physiopathological concepts, a single session of tDCS and FES was likely insufficient to promote neuroplasticity, since this phenomenon requires constant, repetitive, low-frequency stimuli to enable the motor cortex to codify information and remodel itself through learning mechanisms[40–42]. Moreover, brain damage differs in terms of location and size as well as other characteristics among stroke survivors, which can interfere with the results[43–45].

Another explanation for the present findings regards the electrode montage. The cathode in the surpraorbital region may have diminished activity in the prefrontal cortex, which is responsible for motor planning[45] thereby exerting a negative

Table 1. Demographic and clinical characteristics of individuals

Variable	Participants (n=30)
Gender (M/F)	30 (23/7)
Age (years)	61.0 ± 9.7
Weight (kg)	74.1 ± 15.2
Body mass index (kg/m^2)	26.3 ± 4.6
Height (m)	1.67 ± 0.11
Mini Mental State Examination (score)	26 [21 to 29]
Fugl-Meyer scale (score)	65.5 ± 23.6
Ashworth scale (grade)	1 [1 to 3]
Muscle strength TA (grade)	3 [2 to 4]
Hemorrhagic stroke	8 (26.7%)
Ischemic stroke	22 (73.3%)
Left-side hemiparesis	15 (50.0%)
Right-side hemiparesis	15 (50.0%)
Time since stroke (months)	37.0 [28.0 to 86.0]

Data expressed as mean ± standard deviation, median [interquartile range] and frequency and percentage; M/F: male/female.

influence on the motor task solicited. Although the montage employed is well referenced in the literature[46], studies have tested new electrode placement protocols that can diminish the influence of the cathode and enhance the focus of the anode to achieve specific objectives in cortical regions[47, 48].

The issue of the ideal time for the evaluation of a motor task in protocols involving tDCS should also be considered. If the evaluation had been performed during treatment, the results may have been different. Studies have suggested that tDCS during the practice of a task promotes a better motor performance due to neuro-excitatory mechanisms attributed to the immediate change in the membrane potential[49–52].

The analysis of FES also revealed no immediate changes in activity of the TA muscle. According to the literature, the best therapeutic response occurs when FES is administered over a longer period of time. Newsam et al.[53] found a significant improvement in the recruitment of motor units following a three-week FES protocol. Knutson et al.[54] found a significant increase in active ankle dorsiflexion following a six-week FES protocol and Mesci et al.[9] found an increase in ankle dorsiflexion as well as a reduction in spasticity following a four-week FES protocol.

The lack of an immediate effect on static balance in the present investigation is in disagreement with data described in previous studies. Kaski et al.[55] found improvements in balance and gait in individuals with leukoaraiosis following a single session of tDCS combined with physical training. Duarte et al.[56] report improvements in anteroposterior sway with EO and

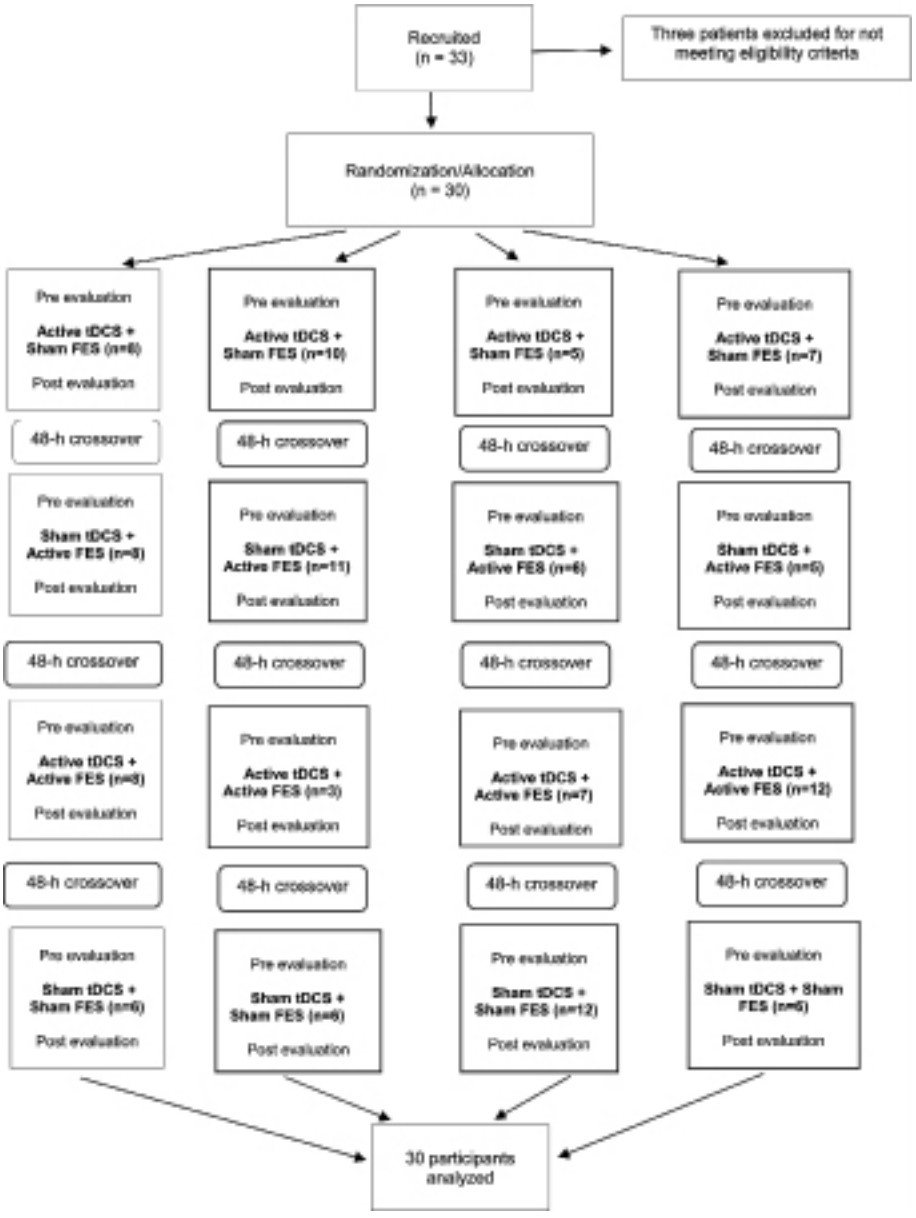

Fig. 1. Flowchart of study.

Table 2. Mean and standard deviation of RMS (root mean square) and median frequency (MDF)

	Intervention		Differences between interventions
	Pre	Post	Adjusted Mean Difference (95% CI)
MDF (hz)			
ta+Fs	103.3 ± 24.9	98.6 ± 23.0	4.42 (1.72 to 7.11)
ts+Fa	101.0 ± 25.3	95.9 ± 24.7	5.09 (1.33 to 8.84)
ta+Fa	100.8 ± 21.2	100.8 ± 22.5	0.01 (−3.40 to 3.42)
ts+Fs	99.3 ± 24.8	95.2 ± 24.4	4.07 (0.13 to 8.01)
RMS (μV)			
ta+Fs	69.7 ± 10.2	68.7 ± 13.7	1.04 (−3.49 to −5.56)
ts+Fa	70.7 ± 12.1	70.7 ± 14.3	−0.01 (−4.26 to 4.22)
ta+Fa	70.9 ± 16.2	68.4 ± 19.0	2.55 (−3.17 to 8.27)
ts+Fs	71.8 ± 12.0	68.3 ± 12.1	3.48 (−1.36 to 8.31)

tDCS anodic (t_a) + FES sham (F_s); tDCS sham (ts) + FES active (F_a); tDCS anodic (t_a) + FES active (F_a); tDCS sham (t_s) + FES sham (F_s).

Table 3. Median. inter-quartile range (25% and 75%) and effect size of stabilometric data observed in antero-posterior (COPap) e medio-lateral (COPml) diretions

Velocity (mm/s)			Pre Intervention	Post intevention	p value	Effect size
ta+Fs	COPap	EO	15.70 (10.98–26.27)	15.97 (10.91–23.94)	0.91	0.02
		EC	13.74 (9.95–21.93)	13.55 (10.11–18.77)	0.17	0.25
	COPml	EO	13.29 (11.90–23.03)	14.19 (11.22–21.30)	0.89	0.02
		EC	12.47 (10.82–21.05)	12.28(11.29–18.18)	0.69	0.07
ts+Fa	COPap	EO	14.00 (10.42–19.52)	13.49 (10.48–20.30)	0.61	0.09
		EC	15.97 (10.78–21.70)	15.33 (10.84–21.57)	0.72	0.07
	COPml	EO	13.07 (10.23–18.32)	13.51 (10.74–18.28)	0.37	0.17
		EC	12.46 (9.91–19.64)	13.39 (10.51–18.37)	0.67	0.08
ta+Fa	COPap	EO	12.08 (9.90–19.00)	12.17 (10.10–17.39)	0.74	0.06
		EC	14.85 (10.67–23.25)	14.11 (11.53–22.62)	0.91	0.02
	COPml	EO	12.70 (10.03–15.02)	11.94 (9.62–18.28)	0.77	0.05
		EC	12.70 (10.62–18.60)	12.19 (11.24–18.45)	0.47	0.13
ts+Fs	COPap	EO	13.67 (10.27–18.78)	13.09 (10.20–19.09)	0.67	0.08
		EC	16.16 (11.18–25.05)	15.54 (11.00–22.68)	0.06	0.35
	COPml	EO	12.36 (10.63–19.30)	12.10 (11.07–15.72)	0.79	0.05
		EC	13.55 (11.68–21.27)	12.74 (10.97–18.17)	0.67	0.08
Median frequency (Hz)						
ta+Fs	COPap	EO	1.95 (1.74–2.51)	2.00 (1.66–2.57)	0.80	0.05
		EC	2.11 (1.74–2.78)	2.08 (1.84–2.80)	0.37	0.17
	COPml	EO	2.92 (1.92–5.57)	3.10 (2.17–4.74)	0.08	0.32
		EC	3.43 (2.30–5.57)	3.49 (2.33–5.31)	0.64	0.08
ts+Fa	COPap	EO	2.08 (1.85–2.53)	2.27 (1.87–2.83)	0.70	0.07
		EC	1.88 (1.67–2.24)	1.92 (1.64–2.53)	0.90	0.02
	COPml	EO	2.73 (2.22–4.39)	2.92 (2.19–5.06)	0.61	0.09
		EC	2.57 (1.85–3.92)	2.63 (1.90–4.42)	0.38	0.16
ta+Fa	COPap	EO	2.08 (1.85–2.42)	2.05 (1.77–2.86)	0.85	0.04
		EC	1.98 (1.66–2.24)	1.92 (1.75–2.68)	0.20	0.24
	COPml	EO	2.96 (2.32–3.79)	2.66 (1.88–5.19)	0.57	0.11
		EC	2.92 (2.13–3.85)	2.27 (1.93–5.02)	0.79	0.05
ts+Fs	COPap	EO	2.14 (1.82–2.81)	2.11 (1.83–2.75)	0.19	0.24
		EC	2.01 (1.67–2.55)	1.92 (1.64–2.39)	0.13	0.28
	COPml	EO	3.38 (2.21–5.38)	3.35 (2.26–5.41)	0.50	0.13
		EC	2.50 (1.90–4.67)	2.63 (1.98–4.23)	0.12	−0.29

COP: center of pressure; ap: anteroposterior; ml: mediolateral; EO: eyes open; EC: eyes close; mm/s: millimeter/seconds; tDCS anodic (t_a) + FES sham (F_s); tDCS sham (ts) + FES active (F_a); tDCS anodic (t_a) + FES active (F_a); tDCS sham (t_s) + FES sham (F_s).

EC, mediolateral sway and the results of the Pediatric Balance Scale in children with cerebral palsy both one week and one month after the conclusion of an intervention involving tDCS and treadmill gait training. Dumont et al.[57] found reductions in anteroposterior sway, sway area and sway velocity in a stroke survivor after a single session of tDCS over the primary motor cortex combined with treadmill training; however, it is not possible to affirm that the immediate effect on balance in this case report was due to tDCS or that tDCS had potentiated the effects of treadmill training, as the author suggests. Immediate effects of tDCS when not combined with other therapies have also been reported. Grecco et al.[58] found significant increases in gait velocity, cadence and body sway in children with cerebral palsy. Sohn et al.[24] found a significant improvement in general postural stability as well as an increase in muscle strength in patients with hemiparesis. Zhou et al.[59] report an increase in gait velocity and a significant reduction COP area and velocity in healthy individuals. Regarding FES, Chung et al.[60] and Hyun et al.[8] report improvements in ankle movements in patients with hemiparesis, but only after training for five days and six weeks, respectively, suggesting the need for long-term repeated stimulation for the achievement of learning.

However, from the results presented in this present study, it can be inferred that the immediate stimulation of the tDCS and FES associated or isolated did not modify the electrical activity of the TA muscle and the static balance of hemiparetic patients due to stroke.

The authors of the present study believe that the lack of a significant change in TA muscle activity and static balance in individuals with hemiparesis after the tDCS and FES protocols may be related to factors such as the amount of stimulus (a single session of the combined methods may be insufficient to generate neuroplasticity), homeostatic defense mechanisms, the electrode montage employed and the chronic nature of the disease (duration of maladaptive plasticity). The reproduction of this study with treatment involving multiple sessions could lead to different results. Nonetheless, the lack of an effect of this technique (tDCS) can contribute to a greater perception in future studies regarding possible methodologies and target population, which are aspects that have not been previously addressed and are important in the context of trials involving noninvasive brain stimulation.

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